

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: STATE CAPITOL BUILDING
ROOM 4202
SACRAMENTO, CALIFORNIA

DATE: MARCH 11, 2010
9:30 A.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

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BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

SACRAMENTO, CALIFORNIA; THURSDAY, MARCH 11, 2010

09:50 AM

CHAIRMAN KLEIN: THANK YOU VERY MUCH. MY NAME IS BOB KLEIN. I'M CHAIRMAN OF THE GOVERNING BOARD OF THE CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE ESTABLISHED BY PROPOSITION 71, AND WE GIVE OUR THANKS TO 7 MILLION VISIONARY CALIFORNIA VOTERS EVERY TIME WE MEET.

I'D LIKE TO HAVE MELISSA KING LEAD US IN THE PLEDGE OF ALLEGIANCE FOLLOWED BY THE ROLL CALL.

(THE PLEDGE OF ALLEGIANCE.)

MS. KING: RICARDO AZZIZ. ROBERT BIRGENEAU. FLOYD BLOOM. GORDON GILL FOR DAVID BRENNER.

DR. GILL: PRESENT.

MS. KING: KIM WITMER FOR DR. BRODY.

DR. WITMER: PRESENT.

MS. KING: JACOB LEVIN FOR SUSAN BRYANT.

DR. LEVIN: HERE.

MS. KING: MARCY FEIT. MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: HERE.

MS. KING: MICHAEL GOLDBERG.

BARRISTERS' REPORTING SERVICE

1 MR. GOLDBERG: HERE.
2 MS. KING: SAM HAWGOOD.
3 DR. HAWGOOD: HERE.
4 MS. KING: BOB KLEIN.
5 CHAIRMAN KLEIN: HERE.
6 MS. KING: SHERRY LANSING.
7 MS. LANSING: HERE.
8 MS. KING: GERALD LEVEY. EXCUSE ME. DR.
9 DAFOE FOR GERALD LEVEY.
10 DR. DAFOE: FOR AZZIZ.
11 MS. KING: I'M SORRY. DONALD DAFOE FOR
12 RICARDO AZZIZ. THAT'S WHY I WAS CONFUSED. THANK
13 YOU. AND YOU'RE PRESENT.
14 TED LOVE.
15 DR. LOVE: HERE.
16 MS. KING: ED PENHOET. PHIL PIZZO.
17 CLAIRE POMEROY.
18 DR. POMEROY: HERE.
19 MS. KING: FRANCISCO PRIETO.
20 DR. PRIETO: HERE.
21 MS. KING: CARMEN PULIAFITO.
22 DR. PULIAFITO: HERE.
23 MS. KING: ROBERT QUINT.
24 DR. QUINT: HERE.
25 MS. KING: JEANNIE FONTANA FOR JOHN REED.

BARRISTERS' REPORTING SERVICE

1 DR. FONTANA: HERE.

2 MS. KING: DUANE ROTH.

3 MR. ROTH: HERE.

4 MS. KING: JOAN SAMUELSON.

5 MS. SAMUELSON: HERE.

6 MS. KING: DAVID SERRANO-SEWELL. JEFF
7 SHEEHY.

8 MR. SHEEHY: HERE.

9 MS. KING: JON SHESTACK, ARE YOU ON THE
10 LINE? OSWALD STEWARD. AND ART TORRES.

11 MR. TORRES: HERE.

12 MS. KING: AND WE DO HAVE A QUORUM.

13 ANYONE JOINING BY PHONE, IF YOU COULD
14 PLEASE PUT YOUR PHONES ON MUTE SO WE DON'T GET THE
15 FEEDBACK THAT WE'RE GETTING, THAT WOULD BE HELPFUL
16 TO THE PROCEEDINGS. THANK YOU.

17 CHAIRMAN KLEIN: ALL RIGHT. THANK YOU
18 VERY MUCH, MELISSA KING. YOU ALWAYS HAVE A
19 MIRACULOUS EXECUTION TO GET THESE EXTRAORDINARY
20 LEADERS THAT MAKE UP THIS BOARD FROM ALL OVER THE
21 STATE AND BRING US TOGETHER FOR OUR MEETINGS.

22 I WANT TO THANK THE LEGISLATURE FOR
23 ALLOWING US TO BE HERE IN THE STATE CAPITOL IN THEIR
24 HEARING ROOMS TODAY. EVERY YEAR WE COME BACK TO THE
25 CAPITOL TO ANSWER QUESTIONS OF LEGISLATORS, TO TALK

BARRISTERS' REPORTING SERVICE

1 ABOUT THE RESEARCH BEING DONE BY THE PHENOMENALLY
2 COMMITTED PHYSICIANS AND CLINICIANS IN THE STATE.
3 IT IS A GREAT PRIVILEGE TO SERVE THE STATE OF
4 CALIFORNIA TO GET CONTINUING INPUT FROM THE
5 LEGISLATURE WHO HAS EXERCISED OVERSIGHT AND
6 LEGISLATIVE AUDITS THAT WE HAVE PERFORMED EXTREMELY
7 WELL ON, AND WE ARE VERY PROUD OF THAT RECORD.

8 IN BEGINNING THE MEETING THIS MORNING, I
9 WOULD LIKE TO MAKE CERTAIN THAT WE GIVE THANKS TO
10 ART TORRES, FORMER STATE SENATOR, WHO IS OUR VICE
11 CHAIR, FOR HIS WORK AND HIS ASSISTANT NICK WARSHAW
12 IN PULLING TOGETHER MEETINGS IN THE CAPITOL.

13 I'D LIKE TO THANK JENNIFER PRYNE AND
14 MELISSA KING AND AMY CHUNG FOR THEIR WORK IN PULLING
15 TOGETHER THIS, AND JOAN SAMUELSON FOR YOUR VERY
16 SPECIAL EFFORT IN JOINING US BY PHONE TODAY.

17 THE BEGINNING OF THIS MEETING WILL FOCUS
18 ON THE PHENOMENAL OPENING WE HAD YESTERDAY OF THE
19 FIRST INSTITUTE IN CALIFORNIA, A CENTER OF
20 EXCELLENCE AT THE UC DAVIS CAMPUS. WE HAVE A
21 PHENOMENAL PIECE OF COVERAGE THAT OCCURRED IN THE
22 *SACRAMENTO BEE* FRONT PAGE ABOVE THE COVER, BACK
23 PAGE, PROPER ATTENTION TO REALLY AN EXTRAORDINARY
24 FACILITY DEDICATED TO THE ADVANCEMENT OF MEDICAL
25 RESEARCH FOR CALIFORNIA, FOR THE COUNTRY, AND FOR

BARRISTERS' REPORTING SERVICE

1 THE PLANET. IT WAS A PRIVILEGE TO BE THERE
2 YESTERDAY.

3 WHAT I'D LIKE TO DO IN OPENING IS JUST
4 REMIND THE BOARD AND THE COMMUNITY OF THE
5 EXCEPTIONAL RESEARCHERS THAT ARE RECIPIENTS OF CIRM
6 GRANTS BECAUSE WE HAVE TREMENDOUS DEPTH AT THE UC
7 DAVIS FACILITY. JAN NOLTA, WHO YOU HEARD FROM IN A
8 TREMENDOUS DEDICATED PROGRAM SPOTLIGHT THIS MORNING
9 TO HUNTINGTON'S DISEASE, LEADS THE STEM CELL CENTER.
10 SHE IS RECIPIENT OF, IN FACT, A CIRM GRANT THAT
11 ALLOWS HER, AS SHE SAID IN HER SPOTLIGHT, TO ADVANCE
12 THE RESEARCH FOR HUNTINGTON'S DISEASE. SHE DOES NOT
13 HAVE OTHER GOVERNMENTAL FUNDING TO BREAK THE CODE ON
14 THIS DEADLY DISEASE.

15 ALICE TARANTAL IS FOCUSING ON KIDNEYS.
16 SHE'S USING CORD BLOOD AND HUMAN EMBRYONIC STEM
17 CELLS.

18 DR. ZHAO IS USING HUMAN EMBRYONIC STEM
19 CELLS IN HIS RESEARCH, AND HE HAS A THREE-YEAR CIRM
20 GRANT. HE'S LOOKING AT ELECTRICAL FIELDS AND THE
21 MIGRATION OF ELECTRICAL CHARGES IN HUMAN STEM CELLS.

22 DR. LAMB RECEIVED A HUMAN EMBRYONIC STEM
23 CELL GRANT AND AN IPS CELL GRANT. HE'S LOOKING AT
24 SYNTHETIC CHEMICAL MOLECULES THAT BIND TO UNIQUE
25 RECEPTORS, PROTEIN MOLECULES ON THE SURFACE OF THOSE

BARRISTERS' REPORTING SERVICE

1 HUMAN EMBRYONIC STEM CELLS. HE IS HIGHLY FOCUSED ON
2 THE BIOMECHANICS OF STEM CELLS AS A CLUE TO LYMPHOMA
3 AND OTHER CANCERS.

4 PAUL KNOEPFLER, DR. PAUL KNOEPFLER IS A
5 RECIPIENT ONE OF OUR GRANTS. HE IS A NEW FACULTY
6 AWARD RECIPIENT, AND HE SPECIALIZES IN STEM CELL AND
7 CANCER-RELATED RESEARCH.

8 DR. PAN HAS FOCUSED HIS WORK ON OVERCOMING
9 LEUKEMIA. HE IS AN M.D./PH.D. THAT REALLY HAS
10 IDENTIFIED MOLECULES THAT SPECIFICALLY RECOGNIZE
11 CANCER STEM CELLS.

12 DR. ZERN IS USING HUMAN EMBRYONIC STEM
13 CELLS. HE'S GENERATING HEPATOCYTES FOR CONTROL OF
14 LIVER DISEASE. HE'S INTERNATIONALLY KNOWN FOR HIS
15 WORK IN EGYPT DEALING WITH LIVER DISEASE.

16 DR. YAMOAH, WE'VE HEARD A SPOTLIGHT FROM
17 HIM ALMOST TWO YEARS AGO ON REGENERATING THE INNER
18 EAR HAIR-LIKE SENSORY CELLS THAT ALLOW US TO HEAR.
19 CRITICAL WORK RECENTLY PUBLISHED IN THE *PROCEEDINGS*
20 *OF THE NATIONAL ACADEMY OF SCIENCES* AND A GRANT
21 RECIPIENT.

22 THIS IS A STORY REPEATED AROUND THE STATE.
23 AS WE GO THROUGH 2009, WE WILL HAVE -- 2010 WE WILL
24 HAVE NINE OPENINGS OF INSTITUTES AND CENTERS OF
25 EXCELLENCE IN CALIFORNIA. IN THIS VOLATILE

BARRISTERS' REPORTING SERVICE

1 FINANCIAL ENVIRONMENT, THAT IS AN INCREDIBLE RECORD,
2 ON-TIME OPENINGS, IN BUDGET. IN FACT, I'M LOOKING
3 AT DR. LEVIN. THEY WERE ABLE TO NEGOTIATE AT UC
4 IRVINE AN ENTIRE NEW FLOOR, AN ADDITIONAL FLOOR
5 WITHIN THEIR BID AND WITHIN BUDGET. SO IT'S A
6 TREMENDOUS BONUS TO THE STATE OF CALIFORNIA AND
7 MEDICAL RESEARCH.

8 BUT THE INDIVIDUAL SCIENTISTS ARE THE ONES
9 THAT ARE CHANGING THE FUTURE OF STEM CELL RESEARCH,
10 CREATING THE HOPE TO REDUCE HUMAN SUFFERING. IT
11 WILL TAKE US MANY YEARS, BUT WE NEED, AS REFLECTED
12 IN THESE SCIENTISTS I'VE HIGHLIGHTED WHO ARE CIRM
13 RECIPIENTS, THE ENTIRE SPECTRUM OF CELLULAR
14 RESEARCH. WE NEED EMBRYONIC STEM CELL RESEARCH, BUT
15 WE NEED MESENCHYMAL CELLS, WE NEED THE WHOLE RANGE
16 OF ADULT STEM CELLS, WE NEED CORD BLOOD CELLS, WE
17 NEED IPS CELLS. EACH OF THE THERAPEUTIC APPROACHES
18 MAY FIND THAT A DIFFERENT CELL TYPE IS APPROPRIATE
19 TO IT. AND I WANT TO EMPHASIZE THAT THAT'S
20 REFLECTED IN EACH OF OUR RESEARCH RECIPIENT
21 INSTITUTIONS, WHETHER IN THE PRIVATE SECTOR OR IN
22 THE PUBLIC SECTOR.

23 I'D LIKE TO ALSO INDICATE THAT ON-TIME
24 CONSTRUCTION, IN-BUDGET CONSTRUCTION, EXTRAORDINARY
25 COMPLEX CONSTRUCTION ONLY HAPPENS WITH DEDICATED

BARRISTERS' REPORTING SERVICE

1 WORKFORCE. THAT WORKFORCE IN CALIFORNIA UNDER
2 PROPOSITION 71 IS A UNION WORKFORCE AS SPECIFIED IN
3 PROPOSITION 71 WHERE WE SPECIFY ESSENTIALLY
4 PREVAILING WAGE REQUIREMENTS.

5 AND WE HAVE SOME GREAT LEADERS FROM THAT
6 UNION WORKFORCE IN CALIFORNIA HERE WITH US TODAY WHO
7 WORK ON THE ACTUAL CONSTRUCTION OF THESE NINE
8 FACILITIES THAT WILL BE COMPLETED THIS YEAR. AND SO
9 IT IS A GREAT PRIVILEGE TO HAVE THEM ACCOMPANYING
10 US.

11 I'M GOING TO HAVE ART TORRES DO THOSE
12 INTRODUCTIONS. I WOULD LIKE TO SAY THAT WE HAVE A
13 COMPLETED STUDY THAT SHOWS OF APPROXIMATELY 100,000
14 JOBS THAT OUR GRANTS APPROVED TO DATE WILL GENERATE
15 OR HAVE GENERATED, WE HAVE ABOUT 13,000 OF THOSE IN
16 THE CONSTRUCTION OF THESE HUGE FACILITIES OF
17 TREMENDOUS INTRICACY WHICH RELY UPON EXTREME
18 TRAINING AND PROFICIENCY IN BUILDING TO CARRY OUT
19 THE KIND OF EXQUISITE RESEARCH WE KNOW IS TAKING
20 PLACE IN OUR RESEARCH FACILITIES IN CALIFORNIA. SO
21 WITH THAT, ART TORRES.

22 MR. TORRES: THANK YOU, MR. CHAIRMAN. I
23 WANTED TO THANK DR. POMEROY. AND AS A CAL AGIE
24 ALUM, I FELT SO PROUD YESTERDAY AT THE OPENING OF
25 THE FACILITY AND SO MOVED BY THE PATIENT ADVOCATES

BARRISTERS' REPORTING SERVICE

1 AND THE DOCTORS IN THEIR MESSAGES. THANK YOU AGAIN,
2 CLAIRE. IT WAS AN INCREDIBLE, INCREDIBLE DISPLAY OF
3 PERSEVERANCE AND COMMITMENT AND HARD, HARD WORK TO
4 GET IT ON TIME. I UNDERSTAND THAT.

5 PART AND PARCEL OF THE MANY WORKERS, MEN
6 AND WOMEN WHO HAVE WORKED IN BUILDING THESE
7 FACILITIES AND ARE STILL BUILDING THESE FACILITIES,
8 NINE HAVE BROKEN GROUND ALREADY. WE'RE IN THE
9 PROCESS NOW OF MAKING SURE THAT WE AS A BOARD
10 RECOGNIZE THE LEADERSHIP OF LABOR AND THE
11 CONSTRUCTION CONTRACTORS AS WELL. AND I WOULD LIKE
12 TO ASK THE REPRESENTATIVES REPRESENTING ALL OF THE
13 WORKERS, WE COULDN'T BRING EVERY UNION UP HERE, BUT
14 REPRESENTING ALL THE WORKERS, WE FELT IT WAS
15 IMPORTANT TO BRING SOME FOLKS HERE TO HONOR THEM IN
16 THEIR COMMITMENT AS THEY'RE BUILDING THESE NEW
17 FACILITIES FOR THE FUTURE.

18 FIRST OF ALL, MY VERY DEAR FRIEND MIKE
19 MCCARRON, WHO IS THE EXECUTIVE SECRETARY-TREASURER
20 OF THE SOUTHERN CALIFORNIA CARPENTERS. PLEASE COME
21 FORWARD. JAY HANSEN, WHO IS HERE, THE LEGISLATIVE
22 DIRECTOR WHO REPRESENTS ALL OF THE STATE BUILDING
23 AND CONSTRUCTION TRADES COUNCIL OF CALIFORNIA.
24 CURTIS KELLY, DISTRICT MANAGER FROM THE NORTHERN
25 CALIFORNIA CARPENTERS, AND JERRY MORALES, WHO IS THE

BARRISTERS' REPORTING SERVICE

1 ASSISTANT REGIONAL DIRECTOR OF THE LABORERS
2 INTERNATIONAL UNION, REPRESENTING ALL THE LABORERS
3 THAT HAVE BEEN WORKING ON THIS PROJECT.

4 AND ALSO FOR THE CONSTRUCTION FROM TURNER
5 CONSTRUCTION, MR. FRANK DAIZOVI, WHO IS THE VICE
6 PRESIDENT AND GENERAL MANAGER. I THINK CLAIRE KNOWS
7 THIS GUY, ROBERT MALDEN, WHO IS THE PROJECT MANAGER
8 OF THE UC DAVIS. IF YOU GENTLEMEN WILL PLEASE COME
9 FORWARD TO THE DAIS. IF YOU COULD COME UP RIGHT
10 BEHIND THE PODIUM, THAT WOULD BE GREAT.

11 GENTLEMEN, WE JUST WANT TO THANK YOU, IT'S
12 SO GOOD TO SEE SO MANY OF YOU AGAIN, FOR THE
13 TREMENDOUS CONTRIBUTIONS THAT YOUR WORKFORCE AND
14 YOUR UNION MEMBERSHIP HAS PROVIDED TO THE PEOPLE OF
15 CALIFORNIA. AND YOU ARE OUR PARTNERS. WE MAY AWARD
16 THE MONEY, BUT YOU HELP BUILD THESE FACILITIES SO
17 THAT SCIENTISTS CAN BEGIN THEIR WORK IN THOSE
18 LABORATORIES ON TIME AS YOU HAVE DONE. SO WE JUST
19 WANTED TO SAY THANK YOU.

20 (APPLAUSE.)

21 MR. TORRES: WE WANT TO PRESENT EACH OF
22 YOU A PLAQUE, WHICH MELISSA HAS. FOR THOSE WHO ARE
23 HERE FROM SOUTHERN CALIFORNIA, WE WILL SHIP IT TO
24 YOU BECAUSE IT'S KIND OF BIG. WE JUST WANTED TO
25 SHOW YOU A SAMPLE OF WHAT YOU WILL BE GETTING.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: (OFF MIC) THE IMAGES ARE OF
2 HUNDREDS OF HUMAN EMBRYONIC STEM CELLS IN VARIOUS
3 STAGES OF DIFFERENTIATION INTO NEURONS. SOME OF THE
4 CELLS BECOME NEURONS WHICH ARE BIG AND OTHERS THAT
5 BECOME PRECURSORS OF NERVE CELLS. (INAUDIBLE.) WE
6 HAVE A NUMBER OF THESE REALLY SPECIAL IMAGES
7 AVAILABLE, AND THIS IS A PARTICULARLY GOOD ONE THAT
8 REFLECTS VERY WELL, I THINK, (INAUDIBLE).

9 MR. TORRES: THANK YOU VERY MUCH. WE'LL
10 START WITH MR. MCCARRON JUST TO SAY A FEW WORDS.
11 YOU FLEW ALL THE WAY FROM LOS ANGELES THIS MORNING.

12 (THE FOLLOWING COMMENTS WERE HEARD
13 OFF MIC AND HEREIN INCORPORATED TO THE BEST OF THE
14 REPORTER'S ABILITY TO HEAR THEM:)

15 MR. MC CARRON: ON BEHALF OF THE 63,000
16 MEMBERS OF THE SOUTHWEST REGIONAL COUNCIL, IT WAS AN
17 HONOR TO PERFORM THOSE DUTIES. AND I'M HERE TO
18 HONOR THEIR SKILL AND PRODUCTIVITY.

19 MR. TORRES: THANK YOU VERY MUCH.

20 MR. MC CARRON: THANK YOU FOR HAVING US.

21 MR. TORRES: MR. KELLY.

22 MR. KELLY: SAME THING. IT WAS
23 INTERESTING TODAY. I WAS HERE EARLIER AND WATCHED
24 THE HUNTINGTON'S THING AND REALIZED HOW MANY PAIR OF
25 HANDS IT TAKES TO CONQUER THIS DISEASE AND WHAT

BARRISTERS' REPORTING SERVICE

1 AWARDS ARE BEING AWARDED BUILDING THE DISEASE HAS
2 ACTUALLY CONQUERED. AND THEN TO THINK THAT THE
3 CARPENTERS AND THE CONSTRUCTION INDUSTRY BUILDS
4 THOSE BUILDINGS, AND THEY'LL GET THE SAME THING. I
5 GOT TO BUILD THAT BUILDING WHERE THAT DISEASE WAS
6 CURED.

7 MR. TORRES: THANK YOU, CURTIS. MR.
8 HANSEN.

9 MR. HANSEN: ON BEHALF OF THE 350,000
10 MEMBERS OF THE STATE BUILDING TRADES, WE ABSOLUTELY
11 ARE EXCITED TO BE PARTNERS WITH YOU. WE'VE GOT
12 TOUGH ECONOMIC TIMES JUST LIKE EVERYBODY ELSE. JOBS
13 MEAN A LOT TO US. TO BE PARTNERS ON A GREAT PROJECT
14 (INAUDIBLE).

15 MR. TORRES: JERRY.

16 MR. MORALES: I ECHO THE SENTIMENTS ON
17 BEHALF OF THE 800,000 MEMBERS ACROSS THE UNITED
18 STATES AND THOSE PEOPLE IN THE COMMUNITY THAT WILL
19 BENEFIT FROM WHAT YOU GUYS ARE DOING, US INCLUDED.
20 SO THANK YOU SO MUCH FOR HAVING US HERE.

21 MR. TORRES: THANK YOU. GIVE OUR BEST TO
22 ROCCO DAVIS AND TO MR. O'SULLIVAN, YOUR GENERAL
23 PRESIDENT. MR. DAIZOVI.

24 MR. DAI ZOVI: I'LL JUST THANK THE CAMPUS.
25 WITHOUT THE CAMPUS STAFF, QUITE FRANKLY, IT WOULD

BARRISTERS' REPORTING SERVICE

1 NOT BE POSSIBLE. THEY WERE GREAT. FANTASTIC TO
2 WORK WITH AND THANK YOU VERY MUCH.

3 MR. TORRES: MR. MALDEN.

4 MR. MALDEN: AGAIN, WORKING WITH THE STAFF
5 AT UC DAVIS, IT WAS MY PLEASURE TO HAVE HANDS ON IN
6 BUILDING THAT PROJECT.

7 MR. TORRES: THANK YOU ALL VERY MUCH
8 AGAIN, GENTLEMEN, AND TO THE MEMBERSHIP OF YOUR
9 UNIONS.

10 (APPLAUSE.)

11 CHAIRMAN KLEIN: SO DR. POMEROY.

12 DR. POMEROY: I WOULD JUST LIKE TO ADD
13 THAT AS WE BUILT THIS FACILITY AT UC DAVIS, WE
14 REALIZED THIS WAS A FACILITY UNLIKE ANYTHING THAT
15 HAS EVER BEEN BUILT BEFORE. THIS IS A ONE-OF-A-KIND
16 FACILITY. AND WHEN YOU ARE BUILDING SOMETHING BRAND
17 NEW, YOU HAVE TO HAVE A TEAM THAT'S WILLING TO
18 REALLY WORK TOGETHER. AND OUR CONSTRUCTION PARTNERS
19 WERE ABSOLUTELY FANTASTIC IN SAYING, "WE WILL MAKE
20 THIS RIGHT BECAUSE WE UNDERSTAND THE IMPORTANCE OF
21 THIS RESEARCH." AND IT WAS A WONDERFUL PARTNERSHIP,
22 AND WE THANK THEM VERY MUCH.

23 CHAIRMAN KLEIN: SO WE THANK ALL 13,000
24 MEMBERS OF THE WORKFORCE THAT HAS DEDICATED A PART
25 OF THEIR LIFE TO MAKING THIS GREAT RESEARCH

BARRISTERS' REPORTING SERVICE

1 POSSIBLE. AND WE THANK THE CONTRACTORS AS WELL FOR
2 THEIR DEDICATION AND LEADERSHIP ON THESE
3 TREMENDOUSLY COMPLEX PROJECTS.

4 IT'S ALMOST MIRACULOUS TO SEE THE
5 COORDINATION OF THE SOPHISTICATED BUILDING SYSTEMS
6 THAT MOVE THROUGH THESE FACILITIES FLAWLESSLY
7 WITHOUT MAJOR CHANGE ORDERS, WITHOUT WORK STOPPAGES
8 BECAUSE THEY WERE THOUGHT THROUGH WITH TREMENDOUS
9 INTELLIGENCE, PLANNING, AND COORDINATION. SO THE
10 PARTNERSHIP BETWEEN THE CONTRACTORS THAT ARE SERVING
11 THESE INSTITUTIONS AND THE UNION WORKFORCE HERE
12 TODAY HAS BEEN AN EXQUISITE ONE WHICH WE ARE DEEPLY
13 APPRECIATIVE FOR.

14 I'D LIKE TO MOVE TO A PRESENTATION OF OUR
15 PRESIDENT ALAN TROUNSON FOR THE PRESIDENT'S REPORT.

16 DR. TROUNSON: (OFF MIC) THANK YOU VERY
17 MUCH, CHAIR. AND IN RESPECT TO THE NEW BUILDING --

18 CHAIRMAN KLEIN: DR. TROUNSON, IF WE COULD
19 ASK THE TECHNICAL STAFF HERE FOR A MOMENT. WHEN I
20 TURN MY MIC OFF, YOU ARE GETTING THIS LOVELY OUTER
21 SPACE VERSION OF OUR MEETING. SO WHAT WE WILL DO IS
22 IF EVERYONE WILL SPEAK LOUDLY, I'LL KEEP THIS MIC ON
23 BECAUSE I THINK THAT DR. TROUNSON'S PRESENTATION IS
24 MORE ATTRACTIVE TO LISTEN TO THAN THE BACKGROUND
25 SOUNDS.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: THANK YOU, CHAIR.
2 YESTERDAY, HAVING SEEN THAT BUILDING PERHAPS IT WAS
3 SIX YEARS AGO, SEVEN YEARS AGO WHEN I WAS HERE, AND
4 SEEING IT IN THIS STATE, YOU KNOW, FOR A SCIENTIST,
5 ALL I WANT TO DO IS GO BACK TO THE LAB. I MIGHT NOT
6 BE IN THIS JOB TOO LONG.

7 DR. POMEROY: THE JOB OFFER AT UC DAVIS
8 STANDS.

9 DR. TROUNSON: THE OTHER THING THAT, OF
10 COURSE, I HAVE A VIEW THAT THERE WILL BE STEM CELL
11 CLINICS THROUGHOUT THE WORLD, THROUGHOUT CALIFORNIA,
12 AND I THINK THAT THIS NEW INSTITUTE IS JUST PERFECT
13 FOR THAT. IT HAS THE GMP FACILITIES THERE AND HAS
14 THE ABILITY TO BRING PATIENTS IN IN A CLINICAL WAY
15 IN THE FUTURE. I ACTUALLY THINK WE'RE LOOKING AT
16 THE REAL FUTURE OF STEM CELL THERAPIES. SO, YOU
17 KNOW, THAT'S MY VIEW OF THINGS. IT'S NOT ALWAYS --
18 I ALWAYS HAVE A BIT OF A RADICAL VIEW OF THINGS, BUT
19 I THINK STEM CELL CLINICS WILL PROLIFERATE. AND I
20 THINK THEY WILL MOVE OUT WITH THESE KINDS OF
21 FACILITIES THAT WE'VE BUILT. THEY'RE FANTASTIC.

22 SO AS USUAL, I'M BEGINNING AND I HOPE YOU
23 CAN SEE, YOU CAN SEE BEHIND ME. I JUST WANT TO
24 BRING TO YOUR ATTENTION THREE STUDIES THAT I'VE SEEN
25 JUST RECENTLY. ONE OF THEM IS ON TELOMERE

BARRISTERS' REPORTING SERVICE

1 ELONGATION. IT WAS A PAPER BY GEORGE DALY'S GROUP
2 FROM BOSTON, A VERY IMPORTANT STEM CELL INSTITUTE
3 THERE. GEORGE HAS BEEN A BIG CONTRIBUTOR TO STEM
4 CELL RESEARCH.

5 TELOMERES APPEAR IN THE CHROMOSOMES, AND
6 SO YOU BEGIN WITH A LONG TELOMERE AND EVENTUALLY,
7 DURING CELL DIVISION, THE TELOMERE IS REDUCED. SO
8 ESSENTIALLY WHEN YOU'RE FINISHED OR WHEN THE
9 TELOMERES GET VERY SHORT, THE CELLS BASICALLY DON'T
10 HAVE ANY LIFE LEFT. SO THIS REALLY FORMATS THE LIFE
11 OF THE CELL, THE TELOMERE. AS YOU CHOP IT DOWN TO
12 SUCCESSIVE CELL DIVISION, IN THE END YOU HAVE A CELL
13 WHICH FACES IT CAN'T SURVIVE AND DEGENERATES AND
14 PASSES ON.

15 SO IF YOU HAVE A PATIENT WITH A DISEASE,
16 AND THIS PARTICULAR DISEASE, RESEARCHERS, GEORGE AND
17 HIS COLLEAGUES, WERE LOOKING AT WERE PATIENTS WITH
18 AN X-LINKED GENETIC DISEASE CALLED DYSKERATOSIS
19 CONGENITA, SO DC IN SHORT. THESE MUTATIONS IN THE
20 DYSKERIN GENE THAT ENCODES AN RNA BINDING PROTEIN
21 WHOSE INACTIVATION CAUSES SHORTENING OF THE
22 TELOMERES, THE SHORTENING OF THAT PIECE ON THE END
23 OF THE CHROMOSOME, AND PREMATURE SENESCENCE OF
24 CELLS. SO THEY DIE MORE QUICKLY. THERE'S SHORTER
25 CELL DIVISION, CYCLES OF CELL DIVISION TIME. AND IT

BARRISTERS' REPORTING SERVICE

1 OCCURS IN MULTIPLE TISSUES.

2 SO THEY'VE MADE IPS CELLS, THE INDUCED
3 PLURIPOTENTIAL STEM CELLS, FROM DC PATIENTS AND
4 SHOWED THAT THEY REACTIVATE TELOMERASE REVERSE
5 TRANSCRIPTASE, THE TRANSCRIPTION GENE, THE TERT
6 GENE, WHICH OVERCOMES THIS CRITICAL LIMITATION IN
7 THE TELOMERASE RNA COMPONENT, THE TERC COMPONENT.

8 SO WHAT IT DOES, IT ADDS BACK THE TELOMERE
9 LINK TO THE CELLS. IF YOU BRING THEM BACK TO THE
10 PLURIPOTENTIAL STATE, WE KNOW THIS IN EMBRYONIC STEM
11 CELLS, THE TELOMERES RELENGTHEN AGAIN TO THEIR
12 NORMAL LENGTH. SO THIS WAS A QUESTION ABOUT IPS
13 CELLS, DO THEY DO THAT, AND INDEED THEY DO IT.

14 SO THEN YOU'VE GOT NOW A CELL WHICH HAS
15 GOT THE NORMAL LENGTH AGAIN, AND THESE CELLS COULD
16 BE USED IN THERAPEUTIC IMPLICATIONS FOR PATIENTS
17 WITH THIS KIND OF DISEASE. SO IT'S A VERY IMPORTANT
18 STUDY BY THE GROUP.

19 MS. SAMUELSON: THIS IS JOAN. IS IT
20 POSSIBLE FOR ALAN TO SPEAK CLOSER TO THE PHONE MIC?

21 DR. TROUNSON: THE SECOND ONE IS A MUCH
22 MORE BASIC STUDY. IT'S ONE THAT WAS FROM THE WANG
23 AND CHANG LABS AT STANFORD AND PUBLISHED IN *GENES &*
24 *DEVELOPMENT*. AND THIS IS ABOUT THE METHYLATION
25 STAGE OF THE HISTONE, THE PROTEIN THAT IS ATTACHED

BARRISTERS' REPORTING SERVICE

1 TO THE DNA. EVERYONE THINKS OF DNA AS A NAKED
2 SPIRAL, BUT ESSENTIALLY IT'S ACTUALLY COVERED BY
3 PROTEINS IN A VERY COMPLEX ARRANGEMENT WHICH
4 DICTATES HOW THE GENES ARE ACTUALLY EXPRESSED.

5 SO THEY SHOWED THAT THE TRIMETHYLATION,
6 PUTTING THE THREE METHYL GROUPS OF HISTONE H3 ON LYS
7 27, IS A KEY FOR CELL FATE REGULATION THROUGH GENE
8 SILENCING. SO IF YOU PUT THAT ON THERE, YOU WILL
9 SILENCE THE GENE BECAUSE THERE'S NO WAY THE GENE CAN
10 THEN BE GOT AT TO ACTUALLY TRANSCRIBE. SO IF YOU
11 SILENCE THAT, YOU SILENCE THE POLYCOMB GROUP OF
12 PROTEINS WHICH ARE REALLY RESPONSIBLE FOR CELL FATE
13 AND CELL GROWTH.

14 AND IT'S REALLY IMPORTANT BECAUSE THEY
15 SHOWED THAT THE DEMETHYLASE TARGET GENES, THE UTX,
16 INCLUDES GENES ENCODING FOR RETINOBLASTOMA-BINDING
17 PROTEINS. AND THE UTX REMOVES THIS AND MAINTAINS
18 THE EXPRESSION OF SEVERAL RETINOBLASTOMA-DEPENDENT
19 PATHWAYS WHICH CONSEQUENTLY HAVE INFLUENCE ON CELL
20 FATE.

21 SO THESE ARE BOTH RELATED TO CANCER AND
22 DIFFERENTIATION, NORMAL DIFFERENTIATION, SO YOU'VE
23 GOT AN INTERSECTION HERE BETWEEN CANCER AND CELL
24 DIFFERENTIATION. SO THIS IS REALLY CRITICAL TO THE
25 UNDERSTANDING OF DIFFERENTIATION AND CANCER. AND

BARRISTERS' REPORTING SERVICE

1 THE MANIPULATION HAS REALLY MAJOR THERAPEUTIC
2 IMPLICATIONS FOR REGENERATIVE MEDICINE AND CANCER.
3 THAT'S WHY WE FUND THIS BASIC STEM CELL RESEARCH.
4 THESE KIND OF THINGS WILL HAVE TREMENDOUS IMPACT
5 DOWNSTREAM.

6 THE LAST ONE I WANTED TO SHARE WITH YOU, I
7 HAVE A PERSONAL DEEP HOLE IN MY HEART, SO TO SPEAK,
8 BECAUSE THIS WAS THE AREA I WAS WORKING ON WHEN BOB
9 KLEIN GOT ME TO COME HERE, AND THIS MIGHT HAVE BEEN
10 MY PAPER. YOU DON'T KNOW HOW THAT MAKES YOU FEEL,
11 BUT YOU FEEL PROUD THAT YOU'RE ON THE RIGHT TRACK;
12 BUT ON THE OTHER HAND, I KIND OF WISH IT WAS MY
13 PAPER THAT I WAS BRINGING FORWARD. IT'S A REALLY
14 NICE PAPER PUBLISHED IN A JOURNAL CALLED *MOLECULAR*
15 *THERAPEUTICS*.

16 AND IT'S THE TRANSPLANTATION OF HUMAN
17 EMBRYONIC STEM CELL-DERIVED ALVEOLAR NONEPITHELIAL
18 TYPE II CELLS. THESE ARE THE TYPE II CELLS THAT ARE
19 AROUND THE ALVEOLI. THEY'RE VERY THIN. THEY'RE THE
20 ONES RESPONSIBLE FOR OXYGENATING THE BLOOD SYSTEM.

21 NOW, THEY ARE ABLE TO PRODUCE PURE CELLS.
22 THESE ARE ALVEOLI TYPE II CELLS, THEY'RE CALLED ATII
23 CELLS, FROM HUMAN EMBRYONIC STEM CELLS. SO THAT'S A
24 BIG CHALLENGE, AND THEY DID THAT BECAUSE THEY HAD
25 SPC, A SPECIFIC PROTEIN THAT ONLY APPEARS IN THE

BARRISTERS' REPORTING SERVICE

1 LUNGS, ATTACHED TO A NEO CONSTRUCT THAT YOU CAN
2 SELECT FOR, AND THIS TRANSGENE WITH A PROMOTOR
3 SEQUENCE FOR TWO OTHER GENES THAT APPEAR IN THE
4 LUNG, AQUAPORIN-5 AND T1 ALPHA. THESE HAVE A CELL
5 SURFACE MUCIN-LIKE GLYCOPROTEIN. YOU CAN ACTUALLY
6 GET A VERY PURE POPULATION OF TYPE II LUNG CELLS.
7 THEY'VE GOT ALL OF THE CHARACTERISTICS. THAT'S
8 EXACTLY WHAT YOU NEED.

9 THESE ATII CELLS PROLIFERATE IN CULTURE
10 AND INCREASE IN THE PRESENCE OF HUMAN RECOMBINANT
11 KERATINOCYTE GROWTH FACTOR. SO THEY'RE ABLE TO
12 MULTIPLY THESE DRAMATICALLY WITH THAT GROWTH FACTOR.
13 WHEN THEY TRANSPLANTED THOSE CELLS INTO BLEOMYCIN
14 TREATED MICE, BLEOMYCIN DESTROYS THOSE TYPE II CELLS
15 AS TAKEN IN BY THE WIND THROUGH THE NOSE. AND THEN
16 IF YOU GIVE THESE HUMAN CELLS, YOU GET QUITE A
17 DRAMATIC RESPONSE SHOWN IN THESE PICTURES HERE.

18 FIRST OF ALL, IN THE WORK THEY'VE HAD NO
19 TUMORS. THAT'S IMPORTANT. NO TUMORS IN ANY OF THE
20 MICE THEY HAD. THEY DELIVERED THESE CELLS BY
21 TRACHEAL INTUBATION. THEY PUT THEM DOWN THROUGH THE
22 TRACHEA. YOU'VE GOT REGENERATION OF TYPE II ALVEOLI
23 CELLS, YOU HAVE BODY WEIGHT RECOVERY IN THE MICE,
24 YOU HAVE ARTERIAL BLOOD OXYGEN SATURATION, SO IT'S
25 COME BACK TO NORMAL. YOU CAN'T HAVE THAT IF YOU'VE

BARRISTERS' REPORTING SERVICE

1 GOT A BLEOMYCIN TREATED MOUSE. DECREASED COLLAGEN
2 DEPOSITION AND INCREASED SURVIVAL.

3 THE BLEOMYCIN IS SHOWN ON THE BLUE BARS.

4 (INTERRUPTION IN AUDIO TRANSMISSION.)

5 DR. TROUNSON: SO THIS, I THINK,
6 DELIVERING CELLS TO HUMANS, THE MOUSE HAS GOT AN
7 EXTREMELY SMALL TRACHEA. IT'S A CHALLENGE. HUMANS
8 HAVE GOT A MUCH BIGGER AIRWAY, SO IT'S A LOT EASIER.
9 BUT YOU CAN ALSO DELIVER THESE CELLS, I BELIEVE,
10 THROUGH THE BLOOD SYSTEM BECAUSE THE BLOOD HAS TO
11 SLOW DOWN WHEN IT GOES THROUGH TO THE LUNG, AND
12 HERE'S A CHANCE TO DRAW IN THOSE CELLS INTO THE LUNG
13 IN A MUCH EASIER WAY.

14 MY PRIORITIES ARE LISTED HERE. I'VE BEEN
15 VERY BUSY ON THE VICE PRESIDENT R&D SEARCH
16 (INAUDIBLE).

17 GRANTEE MEETING WE JUST HAD (INAUDIBLE).
18 IT WAS JUST A BRILLIANT MEETING. (INAUDIBLE).

19 THE DIVERSITY WORKSHOP (INAUDIBLE.) AND
20 ALSO A GERMAN-CALIFORNIA SCIENCE WORKSHOP. (ON MIC)
21 WE'VE BEEN BUSY ON THESE MEETINGS. WE'VE GOT AN
22 ISSCR/CIRM REGULATORY WORKSHOP COMING UP SHORTLY IN
23 JUNE. WE HAVE INTERNATIONAL AND INTERSTATE
24 AGREEMENTS AND PROJECT MONITORING, SO WE'VE BEEN
25 DOING A LOT OF WORK ON OUR INTERSTATE AND

BARRISTERS' REPORTING SERVICE

1 INTERNATIONAL PARTNERS. I THINK WE'VE FINALLY NOW
2 GOT AN AGREEMENT WITH THE NEW YORK STEM CELL
3 FOUNDATION, SO WE'VE DRAWN ANOTHER STATE INTO OUR
4 COALITION, IF YOU LIKE, OF COLLABORATIVE PARTNERS.
5 I THINK THAT WAS ANOTHER BIG AND IMPORTANT STEP
6 FORWARD.

7 THERE HAVE BEEN PATENT ISSUES THAT WE'VE
8 BEEN DEALING WITH AND CIRM ECONOMIC STIMULUS ISSUES.
9 INITIATING THE DISEASE TEAM PROJECTS HAS BEEN A
10 MASSIVE EFFORT. AND PAT OLSON AND HER TEAM HAVE
11 WORKED INCREDIBLY, INCREDIBLY INTENSIVELY WITH ALL
12 THE DISEASE TEAM GROUPS. AND I TELL YOU THEY'RE ALL
13 TAKING OFF IN THE RIGHT DIRECTION. AND I WANTED TO
14 THANK ALL OF THE UNIVERSITY INSTITUTIONS WHO WERE
15 REALLY IN A NEW FORMAT IN THESE DISEASE TEAMS
16 BECAUSE THEY'VE RESPONDED IN SUCH A POSITIVE WAY TO
17 US AND TO THE COMMERCIAL PARTNERS IN ACTUALLY
18 GETTING THINGS STRAIGHT TO VERY PRECISE AND ON THE
19 TRACK TO GO TO THE CLINIC. IT'S NOT NECESSARILY
20 NORMAL THAT THAT HAPPENS IN ACADEMIA. ACADEMICS
21 LIKE TO WANDER. I DID LOVE TO SORT OF INVESTIGATE
22 SOMETHING OFF THE TRAIL, NEW.

23 BUT ON THIS WORK, WE NEED TO STAY ON TRACK
24 TO GET AN IND IN THE TIME THAT'S THERE. AND IT'S
25 DEMANDING. IT'S WHAT THE COMPANIES NORMALLY HAVE TO

BARRISTERS' REPORTING SERVICE

1 DO. AND I HAVE TO SAY THE INSTITUTIONS AND THE
2 LEADERSHIP IN THESE TEAMS ARE VERY FANTASTIC. YOU
3 KNOW, AT TIMES THEY MIGHT HAVE GRIZZLED ABOUT THE
4 PROCESS, BUT THEY'VE EMBRACED IT DRAMATICALLY. THEY
5 REALLY HAVE.

6 CHAIRMAN KLEIN: AND, DR. TROUNSON, I
7 THINK YOU WOULD EXTEND THAT PRAISE TOO TO THE
8 RESEARCH HOSPITALS AND THE RESEARCH INSTITUTES WHO
9 REACHED OUT TO EMBRACE THIS PLAN. SO WE REALLY HAVE
10 THE ENTIRE SCOPE OF THE RESEARCH COMMUNITY THAT
11 YOU'VE INDUCED TO REALLY COLLABORATE IN A PHENOMENAL
12 WAY WITH OUR INSTITUTION AND THE INTERNATIONAL
13 PARTNERS.

14 DR. TROUNSON: THAT'S RIGHT. I HAVE A
15 VIEW THAT THIS IS A KIND OF NEW PARADIGM WHERE
16 ACADEMICS AND BIOTECH INDUSTRY ARE WORKING IN
17 PARTNERSHIP THROUGH A TIME, THROUGH A SPACE KNOWN TO
18 BE A DANGEROUS SPACE FOR SURVIVAL FOR BIOTECH
19 COMPANIES AND ALSO NOT A PLACE WHERE ACADEMICS TEND
20 TO WANDER OR CLINICAL MEDICINE PEOPLE WANDER.

21 I THINK THEY'VE GOT THE ADDED STRENGTH OF
22 EACH OTHER, AND IT'S ACTUALLY WORKING AT THIS POINT.
23 IT'S WORKING BEAUTIFULLY.

24 WE'VE BEEN LOOKING AT DEVELOPING A
25 CLINICAL TRIALS RFA. WE'VE BEEN BUSY WITH THE

BARRISTERS' REPORTING SERVICE

1 BIOTECH INDUSTRY INPUTS TO RFA'S AND GRANT REVIEWS.
2 I NOW HAVE MEETINGS REGULARLY WITH BIOTECH INDUSTRY
3 MEMBERS, AND I'M GETTING A GENERIC FEEL FOR THEIR
4 NEEDS. RATHER THAN JUST GETTING THE INPUTS ONE BY
5 ONE, GETTING GENERIC INPUT. AND IT'S INTERESTING
6 THAT THAT'S ALWAYS -- THAT'S HELPFUL ACTUALLY
7 BECAUSE YOU GET THEM SITTING TOGETHER GIVING YOU A
8 REAL VIEW OF WHAT WE CAN DO FOR THE WHOLE INDUSTRY
9 RATHER THAN WHAT CAN WE SPECIFICALLY DO FOR THAT
10 COMPANY. IT'S A DIFFERENT MESSAGE, AND IT'S AN
11 IMPORTANT ONE.

12 WE'VE BEEN BUSY SORT OF SETTING UP THE
13 CIRM 2010 REVIEW. COMMUNICATIONS HAS BEEN A BIG
14 ISSUE. CIRM SCIENTIFIC CREATIVITY INTERNSHIPS I PUT
15 TO THE CHAIR IN RESPONSE TO SOME YOUNG STUDENTS
16 COMING TO ME ABOUT FELLOWSHIPS. I LIVE IN A WORLD
17 THAT USED TO BE VERY CREATIVE WHERE PEOPLE WHO
18 INHABITED DIFFERENT SPACES, MUSIC, SCIENCE, OR
19 PHYSICS AND MOLECULAR BIOLOGY, TURN OUT TO COME UP
20 WITH THE MOST CREATIVE THINGS. AND I WANTED TO
21 STIMULATE SOME OF THESE YOUNG PEOPLE TO DO THAT AND
22 TO GIVE SMALL SCHOLARSHIPS TO THOSE YOUNG PEOPLE'S
23 CREATIVITY.

24 AND THE CHAIR HAS BEEN VERY SUPPORTIVE IN
25 THAT. I HAVEN'T REALLY SORT OF DEVELOPED ANYTHING

BARRISTERS' REPORTING SERVICE

1 IN DETAIL ABOUT IT. BUT IF YOU WERE GOING TO GO TO
2 TWO OR THREE OF THESE DIFFERENT SPACES IN YOUR
3 SUMMER OR OVER A YEAR, I'D LOVE TO SUPPORT YOU TO DO
4 THAT BECAUSE I THINK WHAT WILL COME OF IT IS
5 SOMETHING VERY DIFFERENT AND SOMETHING VERY SPECIAL.
6 AND WE NEED A LOT OF CREATIVITY AS WELL AS THE HARD
7 YARDS IN THE FRAMEWORK. WE NEED IT ALL, AND I THINK
8 IT'S AN INVESTMENT IN OUR FUTURE.

9 ANYWAY, WE'LL COME BACK TO YOU PERHAPS
10 WITH THAT IN A LITTLE MORE DETAIL, BUT IT'S NOT A
11 LOT OF MONEY, BUT I THINK IT'S A LOT OF OPPORTUNITY
12 FOR CREATIVITY, PARTICULARLY FOR YOUNG PEOPLE WHO
13 ARE NOT QUITE SO CEMENTED IN WHAT THEY'VE GOT TO DO
14 IN LIFE.

15 THIS IS A PICTURE OF THE ISSCR ANNUAL
16 GENERAL MEETING. IT'S ON JUNE 16TH TO 19 IN SAN
17 FRANCISCO. I WANTED TO LET YOU KNOW THAT IT'S
18 HAPPENING. IT'S A MASSIVE MEETING OF THE STEM CELL
19 INDUSTRY FROM AROUND THE WORLD. SO IT'S GOING TO BE
20 A VERY IMPORTANT MEETING.

21 ON THE EXTERNAL REVIEW, THE STRATEGIC PLAN
22 CALLS FOR A REVIEW AFTER THREE YEARS BY A BLUE
23 RIBBON COMMITTEE OF SCIENTISTS, CLINICIANS,
24 ETHICISTS, AND PATIENT ADVOCATES. THE GOALS OF THAT
25 REVIEW ARE TO MEASURE PROGRESS AGAINST STATED

BARRISTERS' REPORTING SERVICE

1 COMMITMENTS, EVALUATE THE STRATEGIC PRINCIPLES, AND
2 MAKE RECOMMENDATIONS FOR CHANGES.

3 SO I'VE ACTUALLY GIVEN THE CHAIR SOME
4 THOUGHTS IN THIS RESPECT. AND I THINK HE'S TAKING
5 IT AROUND TO SEE HOW WELL IT FITS. BUT I THINK
6 THERE'S AN OPPORTUNITY TO GET SOME REALLY TOP-LINE
7 PEOPLE TO REVIEW US. I THINK THEY'RE THERE, THEY'RE
8 WILLING. WHAT WE JUST GOT TO DO IS NOW INITIATE
9 THAT.

10 SO WE'RE BUILDING THAT TEAM OF REVIEWERS,
11 DEVELOPING THE TIMELINES, AND MODELING THE
12 LONG-RANGE PROJECTIONS FOR THE ENTIRE 3 BILLION
13 AUTHORIZATION. SO WE'RE GETTING A COMPLETE PLAN OF
14 WHAT WE CAN ACTUALLY DO WITH THIS \$3 BILLION. IF WE
15 ARE SPENDING IT AT A CURRENT RATE, HOW LONG WILL IT
16 GO? WHAT CAN WE DO WITH IT? DO WE LENGTHEN IT? DO
17 WE SHORTEN IT? WHAT DO WE DO WITH IT? WE NEED TO
18 HAVE A GOOD IDEA AND BRING THIS BACK TO YOU FOR
19 DISCUSSION. REALLY NEEDS A GOOD IDEA OF WHERE WE'RE
20 GOING.

21 COMPLETED GRANT REVIEWS: BASIC BIOLOGY II
22 IS NOW COMPLETED. WE HAD 57 APPLICATIONS. THE
23 DEADLINE WAS IN DECEMBER. THE REVIEW WAS JUST HELD
24 IN FEBRUARY, AND WE'LL BE BRINGING IT TO THE ICOC IN
25 APRIL. AGAIN, I THINK, JEFF, WE HAD A GOOD MEETING

BARRISTERS' REPORTING SERVICE

1 ON THOSE BASIC SCIENCE STUDIES. THERE WERE SOME
2 REALLY TOP-LINE ONES AND SOME THAT WERE NOT REALLY
3 QUITE UP, AS YOU WOULD EXPECT, BUT IT WAS A GREAT
4 MEETING. I THOUGHT THAT THE TEAM THAT WORKED ON
5 THAT GRANT REVIEW, THE REVIEWERS WERE TERRIFIC.

6 UPCOMING GRANT REVIEWS: STEM CELL
7 TRANSPLANTATION AND IMMUNOLOGY. THE REVIEW IS IN
8 APRIL 8TH AND 9TH, AND WE'RE BRINGING THAT TO THE
9 ICOC IN JUNE. WE HAD A TERRIFIC IMMUNOLOGY AND
10 TRANSPLANTATION SESSION AT THE GRANTEE WORKSHOP. IT
11 WAS REALLY, REALLY SUPERB. AND DAVID SACHS IN
12 PARTICULAR WHO LED THAT OFF REALLY GAVE US SOME
13 TERRIFIC INSIGHT INTO TOLERANCE AND WHAT'S REALLY
14 REQUIRED THERE. BUT YOU CAN SEE THAT THE
15 CALIFORNIANS ARE MOVING INTO THIS AREA AND HAVE GOT
16 A VERY WELL DEVELOPED PERSPECTIVE OF IT. SO WE'LL
17 BE INTERESTED IN READING AND REVIEWING THOSE
18 PROJECTS THAT CAME FORWARD.

19 RESEARCH LEADERSHIP AWARDS: WE RECEIVED
20 OUR FIRST APPLICATION, JUST ONE APPLICATION. SO
21 IT'S NOT HIGHLY COMPETITIVE JUST YET, BUT WE HAVE
22 ONE APPLICATION THAT WE WILL DEAL WITH IN REVIEW IN
23 MARCH AND BRING THAT TO THE ICOC IN APRIL, THE
24 OUTCOME.

25 I'VE ACTUALLY MANAGED TO GET ALL THE

BARRISTERS' REPORTING SERVICE

1 TOP-LINE STEM CELL RESEARCHERS IN CALIFORNIA AND
2 AROUND THE WORLD TO BE PART OF THAT REVIEW TEAM.
3 THEY RESPONDED TO MY CALL TO REALLY THE TOP-LINE
4 PEOPLE TO BE AVAILABLE TO HELP US REVIEW THAT.

5 UPCOMING RFA'S: EARLY TRANSLATIONAL II
6 WAS POSTED IN FEBRUARY, RECEIPT OF PREAPPLICATIONS
7 IN MARCH, FULL GRANT APPLICATIONS BY JUNE, AND THE
8 REVIEW IN SEPTEMBER.

9 WE'VE ALSO GOT A TOOLS AND TECHNOLOGIES
10 AND BOTTLENECKS. QUITE A MOUTHFUL. WE'RE POSTING
11 THE RFA IN MARCH/APRIL, RECEIPT OF PREAPPLICATIONS
12 IN MAY, REVIEW IN NOVEMBER, AND ICOC IN JANUARY. SO
13 YOU'VE GOT A BIT OF AN IDEA WHAT'S IN FRONT WITH
14 THESE UPCOMING RFA'S.

15 AND A CLINICAL CONCEPT CLEARANCE, WE'RE
16 PRESENTING THAT TO YOU AT THIS MEETING.

17 REFERRING YOU TO THE WEB SITE ON THE CIRM
18 MODEL FOR CURRICULUM ON STEM CELL SCIENCE, I THINK
19 YOU WILL FIND IT INTERESTING READING.

20 THE MAJOR FACILITY PLAQUES, THIS IS NORMAL
21 THANKS THAT'S THERE WITH THANKS TO THE VOTERS OF
22 CALIFORNIA FOR PASSING PROPOSITION 71, CREATING THE
23 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE,
24 WHICH CONTRIBUTED MAJOR SUPPORT FOR THIS FACILITY.

25 NOW, THIS FACILITIES PLAQUE ON THE UC

BARRISTERS' REPORTING SERVICE

1 IRVINE, THE PROPOSED TEXT IS HERE. LET ME READ IT
2 TO YOU. IT DOESN'T REQUIRE THAT YOU APPROVE IT OR
3 NOT, BUT I WANT TO READ IT TO YOU SO WE CAN GIVE ANY
4 FEEDBACK THAT YOU THINK IS APPROPRIATE.

5 THIS BUILDING EXISTS TO TURN THE PROMISE
6 OF STEM CELL RESEARCH INTO THE REALITIES OF
7 THERAPIES AND CURES FOR THE WORLD'S MOST RAVAGING
8 DISEASES AND INJURIES. THE CREATION OF THIS
9 FACILITY AND THE WORK IT SUPPORTS IS TESTAMENT TO
10 THE PIONEERING SPIRIT AND COMPASSION OF THE PEOPLE
11 OF CALIFORNIA.

12 THE CONSTRUCTION OF THIS STATE-OF-THE-ART
13 FACILITY WAS ENABLED BY THE GENEROSITY OF THE PEOPLE
14 OF THE STATE OF CALIFORNIA. THEIR PASSAGE OF
15 PROPOSITION 71, THE CALIFORNIA STEM CELL RESEARCH
16 AND CURES ACT, CREATED THE CALIFORNIA INSTITUTE FOR
17 REGENERATIVE MEDICINE WHOSE SUPPORT WAS AT THE HEART
18 OF THE CREATION OF THIS FACILITY.

19 THE RESEARCH BEING CARRIED OUT HERE
20 REPRESENTS HOPES TO MILLIONS OF PATIENTS AND THEIR
21 FAMILIES IN CALIFORNIA AND AROUND THE WORLD
22 SUFFERING FROM DEBILITATING DISEASES OR DISABILITY.

23 I THINK THEY'RE VERY NICE WORDS. I DON'T
24 HAVE ANY PROBLEM WITH THEM AT ALL. YOU LET ME KNOW
25 IF IT DOESN'T REALLY SORT OF MEET YOUR APPROVAL.

BARRISTERS' REPORTING SERVICE

1 LET ME KNOW AND WE'LL PASS IT ALONG.

2 WORKSHOPS COMPLETED: A CIRM DIVERSITY
3 WORKSHOP AT DREW UNIVERSITY WAS CHAIRED BY ART
4 TORRES PRECISELY AND EFFICIENTLY. AND I GOT THE
5 OUTCOMES. AND ON TIME, SAYS HIM.

6 WE HAD A CIRM GRANT WRITING WEBINAR WHICH
7 I THOUGHT WAS TERRIFIC. AND THE STAFF, PARTICULARLY
8 JOHN ROBSON AND PAT OLSON AND OTHER MEMBERS OF THE
9 STAFF, I THINK THEY DID A GREAT JOB IN THAT WEBINAR.
10 IT'S AVAILABLE NOW ON OUR WEB SITE. THIS WAS MEANT
11 TO HELP PEOPLE WHO ARE INTERESTED IN WRITING
12 APPLICATIONS FOR RFA'S, PARTICULARLY THOSE PEOPLE
13 WHO ARE IN THE BIOTECH INDUSTRY WHO SOMETIMES FEEL
14 THAT'S CHALLENGING TO DO. WE WANTED TO HELP THEM IN
15 THAT PROCESS.

16 WE HAD THE CIRM GRANTEE MEETING IN SAN
17 FRANCISCO. AS I SAID, IT WAS A FABULOUS MEETING.
18 AND THEN WE HAD A GERMAN/CIRM SCIENCE COLLABORATION
19 MEETING STRAIGHT AFTER THAT ON THE 6TH OF MARCH. SO
20 I HAVEN'T BEEN HOME FOR ABOUT SIX DAYS, BUT IT WAS
21 FULL OF SCIENCE. AND I THINK IT WAS ALL WONDERFUL
22 ACTUALLY.

23 DIVERSITY WORKSHOP AT DREW INCLUDED THE UC
24 MERCED, UC SAN DIEGO, UC RIVERSIDE, UCLA, ONYX
25 PHARMACEUTICALS, AND CIRM STAFF MEMBERS, AND THE

BARRISTERS' REPORTING SERVICE

1 MEMBERS OF THE ICOC ATTENDED.

2 IN TERMS OF THE HIGHLIGHTS, I'M JUST
3 MAKING DOT POINTS OF THOSE. WE'LL GET A REPORT FROM
4 STAFF IN DUE COURSE. THE HIGHLIGHTS: THE NEED FOR
5 AND VALUE OF GREATER DIVERSITY OF DONORS FOR HUMAN
6 EMBRYONIC STEM CELLS AND IPS CELLS.

7 SECONDLY, SUCCESSFUL STRATEGIES FOR
8 RECRUITING PARTICIPANTS IN BASIC RESEARCH AND
9 CLINICAL TRIALS.

10 THIRDLY, THE VALUE OF NICHE CAPACITY FOR
11 SMALLER RESEARCH INSTITUTIONS. WHAT CAN THEY DO
12 THAT ARE VERY SPECIFIC AND VERY USEFUL AND ARE
13 REALLY NATURALLY THEIRS?

14 AND FINALLY, FOUR, SUCCESSFUL MODELS FOR
15 UTILIZING PRACTICE-BASED NETWORKS TO SUPPORT
16 RECRUITMENT IN CLINICAL TRIALS.

17 THEY WERE THE HIGHLIGHTS THAT WERE BROUGHT
18 FORWARD FOR ME.

19 THE GRANTEE WORKSHOP, THERE WERE 450
20 REGISTRANTS, PI'S, TRAINEES, TRAINING AND BRIDGES
21 PROGRAM DIRECTORS, AND SHARED LAB DIRECTORS. THERE
22 WERE 130 ABSTRACTS PRESENTED AS POSTERS, GREAT
23 STUFF. SCIENCE PRESENTATIONS FROM LEADERS IN THE
24 FIELD AND A NETWORKING OPPORTUNITY FOR GRANTEES.

25 I TRIED TO GET THEM TO GIVE US SOME

BARRISTERS' REPORTING SERVICE

1 FEEDBACK ON WHAT ARE OUR DEFICIENCIES IN CIRM AND
2 HOW CAN WE DO IT BETTER. THEY WERE INTERESTED IN
3 TALKING SCIENCE, NOT THAT STUFF, YOU KNOW. IF I
4 WANT FEEDBACK FROM THEM, I HAVE TO DO IT IN SOME
5 OTHER WAY. THIS WAS A SCIENCE THING AND THAT'S WHAT
6 THEY WERE KEENLY INTERESTED IN.

7 THE WEBINAR, THE GOALS WERE TO PROVIDE AN
8 OVERVIEW OF CIRM FUNDING GOALS, EDUCATE RESEARCHERS
9 ABOUT THE GRANT REVIEW PROCESS AND THE NATURE OF THE
10 REVIEW BOARDS, AND PROVIDE EXAMPLES OF SUCCESSFUL
11 INDUSTRY APPLICATIONS AND SOME GUIDANCE ON
12 SUCCESSFUL GRANT WRITING. AND THEY'RE AVAILABLE TO
13 EVERYBODY THROUGH THE CIRM WEB SITE.

14 THE GERMAN/CALIFORNIA WORKSHOP, IT WAS
15 ATTENDED BY 20 GERMAN SCIENTISTS FROM 12
16 INSTITUTIONS, AND WE MANAGED TO GET 12 CALIFORNIA
17 SCIENTISTS TO EXTEND THEIR TIME FROM THE GRANTEE
18 WORKSHOP AND BE INVOLVED. I SAW FIRSTHAND SYNERGIES
19 IDENTIFIED IN AREAS OF NEURAL, CARDIAC, PANCREATIC,
20 AND CARTILAGE/BONE PROJECTS AND ALSO IN
21 BIOENGINEERING. YOU COULD SEE THEM GETTING
22 TOGETHER, CLICKING TOGETHER. AND I THINK THESE WILL
23 BE -- SOME OF THESE WILL BE EXPRESSED, I THINK, IN
24 GRANTS COMING FORWARD IN THE FUTURE. THERE WAS
25 STRONG INTEREST IN IDENTIFYING COLLABORATIVE

BARRISTERS' REPORTING SERVICE

1 PROJECTS ALONG THE DEVELOPMENT PIPELINE ALL THE WAY
2 ALONG FROM THE BASIC THROUGH TO THE CLINICAL WORK.
3 UPCOMING WORKSHOPS: THIS WILL GIVE YOU AN
4 IDEA OF WHAT WE'RE IN FOR AT THE MOMENT. THERE'S
5 ONE FOR MARYLAND IN THE SCIENCE COLLABORATION.
6 THAT'S ON MARCH 11TH AND 12TH. A CIRM CONSORTIUM
7 WHERE WE'RE WORKING WITH THE FDA ON A WEBINAR IN
8 APRIL. THE MRC/CIRM STEM CELL NUCLEAR TRANSFER
9 PARTHENOGENESIS WORKSHOP WILL BE JUNE 13TH AND 14TH.
10 JEANNIE, WILL, SHE PROMISES, BE ALONG AS WE HOPE
11 SOME OF THE OTHER PEOPLE ARE BECAUSE WE'RE GOING TO
12 DISCUSS STEM CELL NUCLEAR TRANSFER. WHAT IS THE
13 ROLE OF THAT NOW? HAS IT BEEN OVERTAKEN BY OTHER
14 THINGS? AND WHAT IS THE STATE TO BRING ALL THE
15 PEOPLE AROUND THE WORLD, FROM THE UK, CHINA,
16 EVERYONE WHO'S BEEN WORKING IN THIS AREA TOGETHER
17 AND TRY AND WORK OUR WAY THROUGH THAT.

18 THERE'S AN ISSCR CLINICAL TRIALS
19 REGULATORY HARMONIZATION WORKSHOP THAT WE'RE VERY
20 INVOLVED WITH WITH THE ISCT. THAT'S JUST BEFORE THE
21 ISSCR ANNUAL MEETING ON JUNE THE 15TH. SO ANYONE
22 WHO HAS INTEREST IN THIS REGULATORY AREA, WE ARE
23 GOING TO DEAL WITH THE DIFFERENCES BETWEEN
24 COUNTRIES, BUT ALSO SOME OF THE ISSUES AND
25 DEFICIENCIES IN OUR OWN SYSTEM. AND THERE ARE SOME

BARRISTERS' REPORTING SERVICE

1 THAT ARE CLEARLY THERE. SEE IF WE CAN MAKE SOME
2 PROGRESS ABOUT ASSISTING THE STEM CELL THERAPIES
3 BECAUSE THEY'RE HAVING A PRETTY ROUGH TIME AT THE
4 MOMENT.

5 MOST OF THEM, I THINK ALL OF THEM, ARE
6 ACTUALLY ON HOLD, ALL THE PLURIPOTENTIAL STEM CELL
7 WORK IS CURRENTLY ON HOLD. AND IT'S A TOUGH TASK.
8 AND GETTING COMPANIES TO STAY ON HOLD FOR A LONG
9 TIME IS REALLY TOUGH ON THEIR SURVIVAL.

10 WE HAVE A CHINA/CIRM SCIENCE COLLABORATION
11 MEETING ON JUNE THE 20TH AFTER THE ISSCR MEETING,
12 AND WE'RE MEETING WITH SPAIN AND THE NETHERLANDS
13 LATER IN THE YEAR. SO THERE'S PLENTY TO DO IN TERMS
14 OF THESE INTERACTIONS.

15 SO IF I CAN INVITE MARGARET FERGUSON
16 FORWARD TO GIVE YOU A BRIEF ON THE BUDGET ALLOCATION
17 AND EXPENDITURE REPORT, CHAIR, IS THAT OKAY?

18 CHAIRMAN KLEIN: THAT WOULD BE FINE.

19 MS. FERGUSON: WELL, GOOD MORNING, MEMBERS
20 OF THE ICOC, CIRM STAFF, AND THE PUBLIC. I'M HERE
21 TODAY TO PRESENT AN UPDATE ON THE FISCAL YEAR
22 2009-10 CIRM SUPPORT BUDGET AND EXPENDITURES THROUGH
23 JANUARY 31ST.

24 ON THE SCREEN BEFORE YOU, YOU WILL SEE
25 THAT WE HAVE A BAR CHART. BASICALLY THE FIRST

BARRISTERS' REPORTING SERVICE

1 GROUPING ON THE FAR RIGHT SIDE IS THE TOTAL CIRM
2 SUPPORT EXPENDITURES THROUGH JULY -- I'M SORRY --
3 JANUARY. THEN WE MOVE TO TOTAL OPERATING EXPENSE
4 AND EQUIPMENT, SALARIES AND BENEFITS BEING THE LAST
5 GROUPING. THE BLUE BAR IS OUR ORIGINAL APPROVED
6 ICOC BUDGET. THE ORANGE BAR INDICATES WHAT WE HAVE
7 RECORDED IN EXPENDITURES THROUGH JANUARY. AND THE
8 YELLOW IS WHAT IS STILL AVAILABLE TO MEET OUR NEEDS
9 THROUGH JUNE 30, 2010.

10 THROUGH JANUARY WE'VE RECORDED TOTAL
11 EXPENDITURES OF \$5.6 MILLION AGAINST OUR \$12.9
12 MILLION BUDGET. WE ALSO HAVE SPENT \$3.8 MILLION OF
13 OUR \$7.4 MILLION BUDGET THAT WAS ALLOCATED FOR
14 SALARIES AND BENEFITS, \$1.7 MILLION OF OUR \$5.5
15 MILLION ALLOCATION FOR OPERATING EXPENDITURES AND
16 EQUIPMENT, AND THAT INCLUDES, BUT IT'S NOT LIMITED
17 TO COST FOR INTERAGENCY AGREEMENTS, OUR CONTRACTS,
18 MEETINGS, INFORMATION TECHNOLOGY, TRAVEL, SUPPLIES,
19 TRAINING, AND COMMUNICATION COSTS.

20 AS NOTED ON THE EXPENDITURE SUMMARY IN
21 YOUR BINDERS, AND I DON'T BELIEVE THAT'S ON THE
22 SCREEN -- LET ME TAKE A -- GOOD. IT'S ON -- WE
23 HAVE EXPENDED 53 PERCENT OF OUR SALARIES AND
24 BENEFITS AND 32 PERCENT OF OUR OPERATING
25 EXPENDITURES AND EQUIPMENT ALLOCATION FOR AN OVERALL

BARRISTERS' REPORTING SERVICE

1 44 PERCENT OF OUR APPROVED BUDGET HAS BEEN SPENT OR
2 RECORDED THROUGH JANUARY. WHEN WE TAKE INTO
3 CONSIDERATION THAT WE HAVE ABOUT \$549,000 IN GOODS
4 AND SERVICES THAT WERE RENDERED IN JANUARY AND NOT
5 YET PROCESSED FOR PAYMENT OR POSTED TO OUR BUDGET
6 REPORT, THAT WOULD INCREASE OUR OPERATING
7 EXPENDITURE AND EQUIPMENT ALLOCATION TO 42 PERCENT
8 BEING SPENT AND AN OVERALL EXPENDITURE AT 48 PERCENT
9 THROUGH JANUARY.

10 AT THIS TIME WE'RE SHOWING AN OVERALL
11 SAVINGS OF ABOUT 10 PERCENT AGAINST OUR APPROVED
12 BUDGET, SALARIES AND WAGES AT A 5-PERCENT SAVINGS,
13 AND OUR OPERATING EXPENSE AND EQUIPMENT AT
14 16-PERCENT SAVINGS. HOWEVER, THERE'S STILL SIX
15 MONTHS OR FIVE MONTHS MORE OF EXPENDITURES THAT WE
16 WILL BE RECORDING THAT WILL INCLUDE COSTS LIKE THE
17 GRANTEE MEETING, OUR SCHEDULED GRANT WORKING GROUPS
18 THAT WE STILL HAVE, THE BALANCES ON SERVICES THAT
19 WILL BE RENDERED FOR OUR CONTRACTS; BUT OVERALL THE
20 16 PERCENT WILL SHRINK, BUT WE ARE DEFINITELY
21 LOOKING AT ABOUT 5-PERCENT SALARY SAVINGS AND
22 OVERALL, AGAIN, RIGHT NOW AT 10 PERCENT AND
23 SHRINKING.

24 NOW I'LL STAND OPEN FOR ANY QUESTIONS THAT
25 YOU MIGHT HAVE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: ANYONE ON THE BOARD HAVE
2 ANY QUESTIONS? THANK YOU VERY MUCH FOR ALL YOUR
3 DEDICATED WORK.

4 MS. SAMUELSON: CAN YOU HEAR ME?

5 DR. TROUNSON: INVITE JOHN ROBSON JUST TO
6 UPDATE YOU WHERE OUR TOTAL FINANCES ARE.

7 MR. SHESTACK: ALAN, CAN YOU HEAR JOAN
8 SAMUELSON ASKING A QUESTION?

9 DR. ROBSON: SO THIS WILL BE VERY BRIEF
10 BECAUSE IT REALLY IS THE SAME STORY I GAVE TO YOU AT
11 THE LAST MEETING. THINGS REALLY HAVEN'T CHANGED
12 MUCH. SO WE'VE MODELED OUR PROJECTED FINANCES FOR
13 EXPENDITURES TO INCLUDE ALL OF THE MONEY THAT WE
14 CURRENTLY HAVE AVAILABLE TO US THROUGH THE SALE OF
15 BONDS. THIS INCLUDES ALL THE PROGRAMS THAT HAVE
16 CURRENTLY BEEN APPROVED AND ARE UNDER WAY PLUS THE
17 PROGRAMS LISTED HERE THAT HAVE BEEN THROUGH CONCEPT
18 APPROVAL: BASIC BIOLOGY, IMMUNOLOGY, THE RESEARCH
19 LEADERSHIP AWARDS, EARLY TRANSLATION, AND TOOLS AND
20 TECHNOLOGY. AND THE DOLLARS LISTED ARE THE TARGET
21 DOLLARS THAT THE ICOC APPROVED.

22 AND, AGAIN, THIS GRAPH WHICH SORT OF
23 SUMMARIZES OUR CURRENT SITUATION SHOWS THAT AT THE
24 END OF -- WE'VE JUST MODELED THIS THROUGH THE END OF
25 THE FISCAL YEAR, THAT'S TO THE END OF JUNE 2011,

BARRISTERS' REPORTING SERVICE

1 THAT WE'LL HAVE ABOUT \$55 MILLION REMAINING IN OUR
2 FUND IF WE DON'T RAISE ANY MORE MONEY, OR THIS
3 DOESN'T ACCOUNT FOR ANY OTHER PROGRAMS THAT COULD BE
4 FUNDED BETWEEN NOW AND THEN.

5 BUT THAT SITUATION IS BASICALLY UNCHANGED
6 FROM WHERE WE WERE LAST TIME. AND IT MEANS WE HAVE
7 ENOUGH MONEY TO CARRY US THROUGH THE FIRST QUARTER
8 OF THE FOLLOWING FISCAL YEAR. ANY QUESTIONS?

9 CHAIRMAN KLEIN: I WOULD POINT OUT TO THE
10 BOARD THAT WE HAVE WORKED WITH THE DEPARTMENT OF
11 FINANCE AND THE TREASURER'S OFFICE, SO THERE IS
12 ADDITIONAL AUTHORITY FOR FUNDS THAT WILL TAKE US
13 BEYOND THAT POINT AND GIVE US THE ADEQUATE BUFFER.
14 WE'VE TALKED WITH DR. TROUNSON ABOUT PROGRAMS
15 ANTICIPATED TO MAKE SURE THAT WE CAN ACCOMMODATE
16 THOSE PROGRAMS IN THE ADDITIONAL FUNDING.

17 DR. TROUNSON: JUST TO FINISH OFF, ALL THE
18 STAFF, OF COURSE, HAVE BEEN INCREDIBLY BUSY, AND
19 THEY'RE A FANTASTIC GROUP OF PEOPLE TO WORK WITH.
20 THERE'S NOW 43 OR 44. DEPENDS HOW YOU COUNT SOME
21 INDIVIDUALS. BUT WE'RE GETTING CLOSE TO THAT 50
22 MARK. IT'S COMING ON STRONG. BUT THEY'RE WONDERFUL
23 PEOPLE, AND I'M REALLY PROUD TO WORK WITH THEM, ALL
24 OF THEM. THANK YOU VERY MUCH.

25 (APPLAUSE.)

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: THIS IS JOAN SAMUELSON.
2 I'M WONDERING IF I CAN BE HEARD.

3 CHAIRMAN KLEIN: WHAT I WOULD LIKE TO DO
4 AT THIS TIME IS MOVE TO ITEM 8, IF WE COULD, PLEASE.
5 I'M GOING TO TAKE UP ITEM 8. AND WE'RE NOT GOING TO
6 TAKE UP ITEM 14 TODAY. WE'RE NOT AT A STAGE OF OUR
7 NEGOTIATIONS WITH THE CANDIDATES TO BE ABLE TO
8 ADDRESS THIS ITEM YET, BUT WE ARE PROGRESSING.
9 THERE'S A LOT OF PROGRESS THAT'S BEEN MADE. ITEM 14
10 WE'RE NOT TAKING UP.

11 EXCUSE ME. STAFF HAS MODIFIED IT. IT IS
12 STILL 14 -- 13. THE STAFF HAS MODIFIED THE NUMBER
13 SINCE THE LAST ROUND. THANK YOU.

14 MS. SAMUELSON: CAN ANYONE HEAR ME? THIS
15 IS JOAN.

16 DR. OLSON: MR. CHAIRMAN, MEMBERS OF THE
17 BOARD, AND THE AUDIENCE, TODAY I'D LIKE TO PRESENT
18 TO YOU THE CONCEPT PROPOSAL FOR A TARGETED CLINICAL
19 DEVELOPMENT RFA AND REQUEST YOUR CONCEPT CLEARANCE
20 FOR THIS PROGRAM. THIS IS AGENDA NO. 8 IN YOUR
21 BINDERS.

22 I JUST WANT TO REMIND YOU, SO THE PURPOSE
23 OF THIS TARGETED CLINICAL DEVELOPMENT PROGRAM IS TO
24 FACILITATE THE DEVELOPMENT OF NOVEL CELL THERAPIES
25 DERIVED FROM PLURIPOTENT STEM CELLS FOR THE BENEFIT

BARRISTERS' REPORTING SERVICE

1 OF PERSONS WITH DISEASE OR SERIOUS INJURY. AND I'M
2 SURE WE ALL REMEMBER WHY PROPOSITION WAS PASSED FOR
3 PLURIPOTENT STEM AND PROGENITOR CELLS TO BRING
4 THERAPIES. AND I THINK YOU MAY ALSO RECALL THAT THE
5 STRATEGIC GOALS THAT WERE OUTLINED IN THE 2006
6 STRATEGIC PLAN THAT YOU APPROVED AND THAT REAFFIRMED
7 WITH THE 2009 STRATEGIC PLAN, ONE OF THE
8 ASPIRATIONAL GOALS, AND I DO PUT IT THAT WAY AS
9 ASPIRATIONAL, WAS ESSENTIALLY THE DEMONSTRATION IN A
10 PHASE II CLINICAL TRIAL OF ESSENTIALLY CLINICAL
11 PROOF OF CONCEPT THAT A PLURIPOTENT-DERIVED CELL
12 THERAPY COULD BRING BENEFIT TO PATIENTS OR COULD
13 POTENTIALLY BRING BENEFIT TO PATIENTS.

14 SO WE LOOK AT THAT RFA AS BEING DIRECTLY
15 RESPONSIVE TO THIS STRATEGIC OBJECTIVE. AND,
16 THEREFORE, THE GOAL OF THIS RFA IS, IN FACT, THE
17 COMPLETION OF EARLY STAGE CLINICAL TRIALS WITHIN A
18 THREE-YEAR TIME PERIOD THAT WILL, ONE, DEMONSTRATE
19 PRELIMINARY SAFETY DATA IN HUMANS AND THAT WILL
20 PROVIDE COMPELLING DATA FOR PROOF OF MECHANISTIC
21 CONCEPT AND/OR EARLY TESTING OF EFFICACY THAT COULD
22 LEAD TO MORE DEFINITIVE CLINICAL STUDIES. SO THAT'S
23 WHAT WE HOPE TO ACCOMPLISH WITH THIS RFA.

24 IN ORDER FOR THIS TO HAPPEN IN THREE
25 YEARS, WHAT WE WOULD DO IS WE WOULD REQUIRE THAT AN

BARRISTERS' REPORTING SERVICE

1 IND ACTUALLY BE FILED BY THE APPLICATION DEADLINE ON
2 THE CELL THERAPY DERIVED FROM PLURIPOTENT STEM CELLS
3 THAT IS PROPOSED FOR FUNDING. AND FOR THOSE
4 APPLICANTS THAT ARE SUCCESSFUL IN THE PEER REVIEW
5 PROCESS AND UPON PRESENTATION TO THIS BOARD AND
6 APPROVAL BY THIS BOARD, WE WOULD REQUIRE THAT THE
7 IND BE ACTIVE; THAT IS, THE IND HOLDER BE ABLE TO
8 ENROLL PATIENTS BEFORE THE ISSUANCE OF THE NOTICE OF
9 AWARD.

10 I THINK YOU HEARD A LITTLE BIT OF THE
11 RATIONALE FOR THIS. AS DR. TROUNSON INDICATED, OF
12 THE THREE STUDIES THAT WE ARE AWARE OF -- OF THE
13 THREE IND'S THAT HAVE BEEN FILED TO DATE FOR
14 PLURIPOTENT-DERIVED CELL THERAPIES, ALL ARE
15 CURRENTLY ON CLINICAL HOLD. ALL ARE CURRENTLY, I'M
16 SURE, IN ACTIVE WORK TO SATISFY THE FDA AS TO THE
17 CONDITIONS THAT WOULD ALLOW THEM TO MOVE FORWARD.
18 THIS IS AN IMPORTANT PART OF IT.

19 SO AS I SAY, THE RATIONALE FOR THESE
20 REQUIREMENTS IS A TIMING ONE. THREE YEARS IS GOING
21 TO BE -- YOU KNOW, I MEAN THAT'S REASONABLE FROM THE
22 START OF THE AWARD FOR YOU TO CONDUCT THE PHASE I
23 AND POSSIBLY A PHASE II A. IT WILL BE CHALLENGING.
24 NEW THERAPIES OF THIS NATURE, ENROLLMENT DOESN'T
25 JUST HAPPEN LIKE THAT, BUT THE NUMBER OF PATIENTS

BARRISTERS' REPORTING SERVICE

1 LIKELY TO BE REQUIRED WILL BE NOT BE HUGE, SO IT AT
2 LEAST IS FEASIBLE.

3 AND THEN WE WOULD ALSO POINT OUT THAT THE
4 UPCOMING DISEASE TEAM AWARDS COULD CAPTURE THOSE
5 PROPOSALS THAT ARE MORE IN THE PRECLINICAL
6 DEVELOPMENT STAGE.

7 I JUST WANT TO HIGHLIGHT FOR YOU ACTUALLY
8 WHERE THIS PROPOSAL WOULD OR WHERE THIS RFA WOULD
9 FALL ON THE SPECTRUM, ON SORT OF OUR STRATEGIC RFA
10 SPECTRUM OF ACTIVITIES, HOW IT FALLS IN THIS STAGE.

11 I THINK YOU ARE AWARE OF WHERE THE EARLY
12 TRANSLATIONAL FALLS. THE DISEASE TEAM RESEARCH
13 AWARDS, THE FIRST ONE THAT YOU APPROVED HAD AS A
14 GOAL AN IND FILING. THE UPCOMING DISEASE TEAM II
15 RESEARCH AWARDS THAT WE HOPE TO BRING TO YOUR
16 ATTENTION MID TO LATE SUMMER FOR CONCEPT APPROVAL
17 WOULD ESSENTIALLY COVER PRECLINICAL DEVELOPMENT AND
18 CLINICAL DEVELOPMENT ACTIVITIES. BUT THIS ONE IS
19 SPECIFICALLY TARGETED FOR THOSE APPLICATIONS USING
20 PLURIPOTENT-DERIVED CELL THERAPIES THAT HAVE AN IND
21 FILED, ACTIVE BY THE START OF THE AWARD, AND BY THE
22 DEMONSTRATION OF SOME PROOF OF CLINICAL CONCEPT,
23 WHICH COUNTS AS AN EARLY WHAT'S CALLED EARLY
24 CLINICAL STUDY BEFORE GOING ON TO MORE DEFINITIVE
25 STUDIES.

BARRISTERS' REPORTING SERVICE

1 THE SCOPE OF THE AWARD I THINK I'VE
2 ALREADY INDICATED TO SOME EXTENT, BUT IT IS FOR THE
3 CONDUCT OF THE EARLY STAGE CLINICAL TRIALS AND FOR
4 SUPPORTING ACTIVITIES THAT WILL, ONE, PROVIDE
5 IMPORTANT ADDITIONAL INFORMATION ON THE CLINICAL
6 QUESTION.

7 WE HAD A VERY INSPIRING TALK FROM OUR
8 KEYNOTE SPEAKER AT THE GRANTEE MEETING FROM DR.
9 SUSAN DESMOND-HELLMAN. AND I THINK YOU ALL KNOW SHE
10 WAS THE FORMER VICE, I DON'T KNOW IF HER TITLE WAS
11 PRESIDENT OR VICE PRESIDENT OF PRODUCT DEVELOPMENT
12 AT GENENTECH, BUT SHE WAS BASICALLY, BEFORE SHE TOOK
13 ON THE CHANCELLORSHIP AT UCSF, SHE WAS HEAD OF ALL
14 THE PRODUCT DEVELOPMENT ACTIVITIES AT GENENTECH.
15 AND THE POINT THAT SHE MADE VERY CONVINCINGLY IS
16 THAT WHEN YOU TAKE EXPERIMENTAL THERAPIES INTO
17 PATIENTS, YOU HAVE A RESPONSIBILITY TO LEARN ALL YOU
18 CAN ABOUT THE DISEASE, ABOUT THE PROPOSED THERAPY
19 FROM THAT STUDY. YOUR TRIAL MAY NOT BE SUCCESSFUL
20 IN THE SENSE THAT YOUR CANDIDATE THERAPEUTIC MAY NOT
21 SHOW ADEQUATE SAFETY, BUT YOU WILL LEARN SOMETHING
22 IF YOU DESIGN IT CORRECTLY.

23 MS. SAMUELSON: THIS IS JOAN SAMUELSON.
24 CAN I BE HEARD ON THIS CALL?

25 CHAIRMAN KLEIN: YES, YOU CAN, JOAN.

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: GOOD. I'M ON THE CELL.
2 MY HOME LINE ISN'T WORKING.

3 CHAIRMAN KLEIN: CAN YOU HEAR DR. OLSON,
4 JOAN?

5 MS. SAMUELSON: YES, I CAN ON THIS LINE.

6 CHAIRMAN KLEIN: CAN YOU HEAR DR. OLSON?

7 MS. SAMUELSON: YES.

8 CHAIRMAN KLEIN: SO IF THE STAFF WOULD
9 PLEASE PUT A SIDE CALL INTO JOAN SAMUELSON. HER
10 LINE DOESN'T SEEM TO BE FULLY FUNCTIONING.

11 MS. SAMUELSON: I'M GOING TO CLOSE THAT
12 LINE. I CAN HEAR PAT, BUT I CAN'T BE HEARD. I'LL
13 SHUT THAT OFF AND JUST TALK ON MY CELL FOR NOW.

14 CHAIRMAN KLEIN: THAT'S FINE. IF STAFF
15 WILL JUST FOLLOW UP WITH A CALL. EXCUSE ME, DR.
16 OLSON, IF YOU WILL CONTINUE.

17 DR. OLSON: SO AS I SAID, I THINK IT'S
18 IMPORTANT THAT WE FUND THE ACTIVITIES TO ALLOW
19 INVESTIGATORS TO PERHAPS CONDUCT ADDITIONAL STUDIES
20 WHETHER IT'S ON SAMPLES OBTAINED OR WHAT THAT WILL
21 HELP ADDRESS THE CLINICAL QUESTION.

22 ANOTHER THING IS WE WOULD FUND ACTIVITIES
23 THAT ENABLE THE CLINICAL STUDY. I CITE, FOR
24 EXAMPLE, CGMP PRODUCTION OR OPTIMIZATION OF
25 PRODUCTION OF THE CANDIDATE THERAPEUTIC FOR THE

BARRISTERS' REPORTING SERVICE

1 PROPOSED TRIALS. I WILL REMIND THIS BOARD THAT CIRM
2 IS ACTUALLY ONE OF THE FEW ORGANIZATIONS THAT
3 DOESN'T JUST FUND A CLINICAL STUDY, BUT FUNDS ALL
4 THE ACTIVITIES THAT ARE ACTUALLY NECESSARY TO RUN A
5 CLINICAL STUDY. AND SO THAT IS REALLY A UNIQUE
6 ATTRIBUTE OF THE FUNDING WE PROVIDE. AND THAT WAS
7 ACTUALLY MADE VERY CLEAR TO US IN THE FIRST DISEASE
8 TEAM RESEARCH AWARDS WHERE, YOU KNOW, WE'VE HAD
9 INVESTIGATORS COME UP TO US AND TELL US THEY SIMPLY
10 COULD NOT DO THE KIND OF THING THEY WERE DOING
11 BECAUSE THEY WOULD HAVE TO GET FIVE DIFFERENT
12 GRANTS.

13 AS YOU KNOW, IN TODAY'S FUNDING
14 ENVIRONMENT, THIS IS A CHALLENGING ACTIVITY. SO IT
15 WOULD DO THAT.

16 WHAT IT WOULD NOT DO IS IT WOULD NOT FUND,
17 FOR EXAMPLE, THE CONDUCT OF PIVOTAL STUDIES. IT
18 WOULD NOT FUND, FOR EXAMPLE, THE SCALE-UP OR
19 PRODUCTION FOR PIVOTAL STUDIES. I WANT TO PUT A BIT
20 OF A RATIONALE FOR THIS, AND, AGAIN, I'LL CITE
21 ACTUALLY. SO OUR FINAL KEYNOTE SPEAKER AT THE
22 GRANTEE MEETING WAS DR. COREY GOODMAN, WHO I THINK
23 MANY OF YOU MAY KNOW HAS BEEN INVOLVED IN A NUMBER
24 OF SUCCESSFUL START-UPS, WAS MOST RECENTLY AT PFIZER
25 IN CHARGE OF A STEM CELL THERAPY UNIT, AND NOW MORE

BARRISTERS' REPORTING SERVICE

1 RECENTLY, I BELIEVE, IS ON THE BOARD OF IPERIAN. AM
2 I CORRECT ABOUT THAT? SO WHAT HE DID IS HE TALKED
3 ABOUT DRUG DEVELOPMENT AND IT WAS INTERESTING.

4 AND YOU KNOW THAT ONE BILLION DOLLAR
5 FIGURE YOU HEAR TOSSED AROUND ALL THE TIME ABOUT THE
6 COST OF DRUG DEVELOPMENT. HE INDICATED IT WAS
7 LARGER, AND I WON'T TELL YOU HOW MUCH LARGER BECAUSE
8 IT WAS A LITTLE BIT FRIGHTENING. BUT, YOU KNOW,
9 PART OF THE THING WAS IT'S ALWAYS THE BALANCE.
10 COMPANIES ALWAYS WANT -- COMPANIES WHO ARE USUALLY
11 THE PRIMARY DEVELOPER OF DRUGS ALWAYS WANT TO MOVE
12 FORWARD AS FAST AS POSSIBLE AND BE READY WHEN THE
13 FIRST TRIAL IS SUCCESSFUL TO MOVE ON TO THE NEXT
14 ONE, SO THEY DO A LOT OF ACTIVITIES AT RISK.

15 AND GIVEN THE PROBABILITIES OF TECHNICAL
16 SUCCESS, THAT CAN BE A VERY RISKY PROPOSITION. SO
17 HE BASICALLY WAS POINTING OUT THAT, YOU KNOW, YOU DO
18 HAVE TO BALANCE DOING ACTIVITIES AT RISK GIVEN THE
19 FACT THAT A LOT OF STUDIES ARE NOT SUCCESSFUL IN THE
20 SENSE OF MEETING THE END POINT THAT WOULD ALLOW THEM
21 TO PROCEED. MAYBE SUCCESSFUL AS WE HOPE IN AT LEAST
22 LEARNING SOMETHING ABOUT THE DISEASE. SO WE WANT TO
23 MAKE SURE THAT WE FUND THE IMPORTANT ACTIVITIES
24 NECESSARY TO GET THE OUTCOMES WE WANT FOR THIS
25 STUDY, BUT NOT THOSE THAT CAN BE DONE SUBSEQUENTLY.

BARRISTERS' REPORTING SERVICE

1 THE INVESTIGATOR -- I MEAN THE ELIGIBILITY
2 CRITERIA IS OUR TYPICAL ELIGIBILITY CRITERIA THAT
3 WAS AGREED TO WITH THIS BOARD AS THE RESULT OF A
4 STUDY WITH A TASK FORCE, SO THAT'S TYPICAL. THE
5 PERCENT EFFORT REQUIREMENTS, I MEAN FOR THIS KIND OF
6 THING WE WANT 30-PERCENT EFFORT FROM THE PRINCIPAL
7 INVESTIGATOR BECAUSE ESSENTIALLY CLINICAL
8 DEVELOPMENT IS ALWAYS A TEAM AND A MULTIDISCIPLINARY
9 ACTIVITY. WE WILL HAVE A CO-PI.

10 IT IS OPEN TO BOTH ACADEMIC NONPROFIT AND
11 FOR-PROFIT INSTITUTIONS. YOU WILL BE DELIGHTED TO
12 SEE THAT WE WILL SIMPLY USE THE LOI MECHANISM TO
13 NOTIFY US. WE DON'T FORESEE AN AVALANCHE OF
14 APPLICATIONS THAT WILL MEET THE REQUIREMENTS FOR
15 THIS PARTICULAR STUDY OR THIS PARTICULAR RFA.

16 THE AWARD INFORMATION THAT WE ARE
17 PROPOSING IS THE FOLLOWING: CIRM FUNDING WILL BE
18 THE LESSER OF 25 MILLION FOR A GIVEN STUDY OR 50
19 PERCENT OF THE TOTAL COST OF THE PROPOSED PROGRAM.
20 AND I WOULD REMIND YOU ALL THAT CIRM-FUNDED RESEARCH
21 IS TO BE CONDUCTED IN CALIFORNIA. THERE WILL BE A
22 MATCHING FUND REQUIREMENT. CLINICAL DEVELOPMENT,
23 PARTICULARLY CLINICAL DEVELOPMENT OF CELL THERAPIES
24 AND OF PLURIPOTENT-DERIVED CELL THERAPIES, IS AN
25 EXPENSIVE PROPOSITION AT THIS STAGE.

BARRISTERS' REPORTING SERVICE

1 AS IT IS, I WOULD POINT OUT THAT FOR
2 ALMOST ANY DRUG DEVELOPMENT, EVEN A SMALL MOLECULE,
3 AT THE EARLY STAGES OF CLINICAL DEVELOPMENT, IT IS
4 MORE EXPENSIVE. SO WE ARE HAVING A MATCHING FUND
5 REQUIREMENT WHERE CIRM AND THE APPLICANT FUNDING
6 CONTRIBUTIONS TO BE REASONABLY DISTRIBUTED OVER THE
7 AWARD PERIOD. THIS IS SOMETHING WE CAN NEGOTIATE IF
8 THERE'S A SUCCESSFUL APPLICANT.

9 MR. SHESTACK: DO THE MATCHING FUNDS NEED
10 TO COME FROM CALIFORNIA?

11 DR. OLSON: NO. THE MATCHING FUNDS DO NOT
12 NEED TO BE SPENT IN CALIFORNIA. THAT'S THE POINT OF
13 IT.

14 MR. SHESTACK: THEY DON'T NEED TO
15 ORIGINATE IN CALIFORNIA EITHER?

16 DR. OLSON: NO, THEY DO NOT. THE MATCHING
17 FUNDS CAN COME FROM WHEREVER.

18 SO JUST TO GIVE YOU AN EXAMPLE OF WHAT WE
19 MEAN BY THAT, IF THE PROGRAM AS PROPOSED TO REACH
20 THE GOAL OF THE RFA IS A \$40 MILLION PROGRAM, THE
21 CIRM FUNDING WOULD BE \$20 MILLION. IF THE PROGRAM
22 AS PROPOSED TO MEET THE GOAL OF THE APPLICATION IS A
23 \$75 MILLION PROGRAM, CIRM FUNDING WILL BE 25
24 MILLION, AND THE APPLICANT WILL BE EXPECTED TO
25 INDICATE HOW THEY CAN COME UP WITH THE OTHER 50

BARRISTERS' REPORTING SERVICE

1 MILLION AND WHAT THAT'S FOR.

2 SO THIS WILL BE AN ACTIVITY. THERE WILL
3 BE AN ACTIVITY -- CIRM FUNDING WILL BE 25 MILLION OF
4 A \$75 MILLION PROGRAM AND THE OTHER 50 MILLION WILL
5 BE THE RESPONSIBILITY --

6 MS. SAMUELSON: THIS IS JOAN. SORRY TO
7 INTERRUPT. CAN I BE HEARD ON THIS LINE NOW?

8 MS. KING: JOAN, CAN YOU HEAR US?

9 MS. SAMUELSON: YES, I CAN. SOUNDS LIKE
10 YOU CAN HEAR ME ON THIS LINE NOW. GREAT. JON
11 SHESTACK IS ALSO TRYING TO BE HEARD, I THINK.

12 CHAIRMAN KLEIN: JOAN, WE JUST HEARD FROM
13 JONATHAN. HE ASKED A QUESTION WHICH WAS ANSWERED.

14 MR. SHESTACK: THEY CAN HEAR ME NOW.
15 WHATEVER THE PROBLEM WAS ON THE LINE IS FINE.

16 DR. OLSON: SO THERE WILL BE AN
17 ACTIVITY-BASED BUDGET, SO WE WILL KNOW WHAT
18 ACTIVITIES WILL BE FUNDED BY CIRM, WHAT ACTIVITIES
19 WILL BE FUNDED BY THE APPLICANT THEMSELVES OR BY THE
20 SUCCESSFUL APPLICANT. SO THAT WILL BE PART OF THIS
21 PROGRAM.

22 I REITERATE AGAIN THERE WILL BE AN ACTIVE
23 IND BEFORE THE ISSUANCE OF NOTICE OF AWARD. THEY
24 HAVE TO BE ABLE TO ENROLL PATIENTS BY THE TIME THEY
25 START THIS PROGRAM IN ORDER TO REALLY REALISTICALLY

BARRISTERS' REPORTING SERVICE

1 HAVE A CHANCE OF BEING ABLE TO COMPLETE THE GOAL OF
2 THE PROGRAM WITHIN THREE YEARS, SO I THINK THAT'S
3 APPROPRIATE.

4 AND THEN WE WOULD PROPOSE THAT WE COMMIT
5 UP TO \$50 MILLION TO THE PROGRAM OVERALL TO FUND ONE
6 TO TWO MERITORIOUS PROGRAMS.

7 THE AWARD MECHANISM WOULD BE A LOAN IF A
8 FOR-PROFIT ORGANIZATION IS THE APPLICANT
9 ORGANIZATION. AND I WOULD POINT OUT THAT WHATEVER
10 ORGANIZATION IS THE IND, ANOTHER WAY TO LOOK AT
11 WHAT'S HERE IS WHATEVER ORGANIZATION IS THE IND
12 HOLDER IS THE APPLICANT ORGANIZATION. SO I THINK
13 THAT'S A FAIR THING. AND, AGAIN, IF THE FOR-PROFIT
14 HOLDS THE IND, THEN THE PI OBVIOUSLY HAS TO BE AN
15 EMPLOYEE OF THE FOR-PROFIT ORGANIZATION. AND AS
16 USUAL, IF THE PI IS FROM A NONPROFIT OR AN ACADEMIC
17 ORGANIZATION THAT HOLDS THE IND, THAT WOULD BE A
18 GRANT.

19 THE PROVISIONAL TIMETABLE IS RELEASE OF
20 THE RFA, I'D SAY, EARLY MAY. LOI DUE IN JUNE.
21 APPLICATIONS DUE IN JULY. REVIEW OF APPLICATIONS IN
22 OCTOBER. I'M SITTING HERE LOOKING AT OUR REVIEW
23 SCHEDULE, SEPTEMBER, OCTOBER, NOVEMBER. SO IT WILL
24 BE A BUSY TIME FOR REVIEWERS. AND ICOC APPROVAL FOR
25 FUNDING IN DECEMBER.

BARRISTERS' REPORTING SERVICE

1 SO WHAT I'D LIKE TO DO IS REQUEST APPROVAL
2 OF THE CONCEPT PLAN FOR THE CIRM TARGETED CLINICAL
3 DEVELOPMENT AWARD WITH A BUDGET OF UP TO 50 MILLION,
4 AND I'D BE HAPPY TO TAKE ANY QUESTIONS.

5 CHAIRMAN KLEIN: THANK YOU, DR. OLSON, FOR
6 THIS PRESENTATION. OBVIOUSLY THIS IS A GREAT
7 MILESTONE FOR THIS AGENCY.

8 I'D LIKE AS A FRAMEWORK FOR THIS
9 DISCUSSION TO SUGGEST THAT SINCE THIS IS THE FIRST
10 PROGRAM OF THIS TYPE, I'D LIKE US TO CONSIDER THESE
11 MILESTONES AND ANY MOTION IN THE CONTEXT OF GIVING
12 THE PRESIDENT SOME DISCRETION. AS WE GO THROUGH THE
13 PROCESS AND THE APPLICATIONS, WE MAY BE IN A
14 SITUATION, FOR EXAMPLE, WHERE YOU HAVE A PI AT 20
15 AND A CO-PI AT 30 PERCENT. I DON'T THINK THAT'S THE
16 KIND OF THING THAT SHOULD PREVENT AN APPLICATION
17 THAT THE PRESIDENT THINKS IS MERITORIOUS FROM COMING
18 IN.

19 SO I WOULD REALLY ENCOURAGE US THAT USING
20 THESE AS GUIDELINES FOR THE PRESIDENT TO HAVE SOME
21 DISCRETION AND REFINING THEM, AND IN INTERFACING
22 WITH WHAT IS ACTUALLY ACCEPTED NOT TO HAVE SOME
23 TECHNICAL DEVIATION THAT IS NOT SUBSTANTIVE DEFEAT
24 AN OTHERWISE MERITORIOUS PROPOSAL.

25 DR. PRIETO.

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: IT SEEMS TO ME THAT, IF I
2 UNDERSTAND CORRECTLY, THERE HAS TO BE BOTH AN IND,
3 AN ACTIVE IND APPLICATION, AND FUNDING FROM OTHER
4 SOURCES IN HAND BEFORE ANY CIRM MONEY WOULD GO TO
5 THE GRANTEE; IS THAT CORRECT?

6 DR. OLSON: WELL, NO, I DIDN'T SAY THAT
7 THE APPLICANT HAD TO HAVE FUNDS IN HAND.

8 DR. PRIETO: COMMITMENTS.

9 DR. OLSON: AS WE HAVE DONE WITH OTHER
10 ORGANIZATIONS, WE DISCUSS WHAT MONEY IS AVAILABLE.
11 THERE CAN BE MADE -- MILESTONES CAN BE PUT IN PLACE
12 TO SAY THEY MUST HAVE X AMOUNT OF FUNDING BY X DATE.
13 YOU KNOW, ONE CAN COME UP WITH FINANCIAL MILESTONES.

14 DR. PRIETO: IT JUST SEEMED TO ME TO BE
15 PRETTY CHALLENGING THRESHOLDS, AND I WONDER IF WE
16 HAVE SOME IDEA OF HOW MANY ACTUAL CANDIDATES THERE
17 MIGHT BE OUT THERE.

18 DR. OLSON: THERE WILL BE VERY FEW
19 APPLICANTS, I WOULD ANTICIPATE, FOR THIS RFA.

20 DR. TROUNSON: IT'S LIKELY TO BE -- AS FAR
21 AS WE KNOW, LIKELY TO BE A MAXIMUM OF THREE, BUT
22 SOMETIMES IT'S SURPRISING, THAT YOU SUDDENLY HAVE
23 ANOTHER ONE THAT APPEARS VERY QUICKLY, PARTICULARLY
24 IN THIS SPACE WHERE PEOPLE TEND TO DO SOME OF THE
25 PRELIMINARY WORK AT A LEVEL BELOW THE RADAR, SO TO

BARRISTERS' REPORTING SERVICE

1 SPEAK. SO IT WAS ONE OF THE THINGS THAT WE REALLY
2 WANTED TO FIND OUT HOW MANY WERE IN THAT SPACE, BUT
3 WE KNOW THAT THERE ARE THREE THAT COULD APPLY.

4 MS. SAMUELSON: ON THAT NOTE, ARE THERE
5 GRANTEE -- PROSPECTIVE GRANTEES INDICATED THAT THEY
6 WOULD MEET THESE GRANT CRITERIA, THEY WOULD BE
7 ENTHUSIASTIC ABOUT APPLYING FOR SUCCESSFUL GRANTS?

8 DR. TROUNSON: I THINK PRETTY MUCH THAT'S
9 RIGHT, JOAN. BUT IF YOU ASK, IF YOU ACTUALLY ASK A
10 PARTICULAR COMPANY FOR DETAILS, WHICH IS NOT WHAT WE
11 DO, I THINK THEY MIGHT SUGGEST, YOU KNOW, RELAXATION
12 OF THIS, THAT, AND THE OTHER, OR SOME CHANGE. BUT I
13 THINK THIS REPRESENTS A REASONABLY ATTRACTIVE -- IT
14 WOULD BE REASONABLY ATTRACTIVE FOR AT LEAST TWO OR
15 THREE OF THOSE ENTITIES THAT CURRENTLY HAVE AN IND
16 FILED TO BE INTERESTED IN IT.

17 WHETHER THERE'S SOMETHING IN OUR IP
18 REGULATIONS OR OTHERWISE THAT WILL PREVENT THEM, WE
19 CAN'T TELL. I'M NOT AT THAT STAGE. IT CAN'T GET
20 DOWN TO THOSE KIND OF DETAILS AND WON'T UNTIL WE
21 RELEASE THE APPLICATION. IT'S INAPPROPRIATE TO GO
22 TOO DEEP ON THAT.

23 CHAIRMAN KLEIN: BEFORE ANYONE BRINGS UP
24 ANY HYPOTHETICAL EXAMPLE OF ANYTHING WE'VE
25 PREVIOUSLY FUNDED, PLEASE REMEMBER ONLY BRING UP

BARRISTERS' REPORTING SERVICE

1 EXAMPLES THAT YOU ARE NOT IN CONFLICT WITH IN ANY
2 WAY.

3 I BELIEVE DR. STEWARD HAS A POINT AND THEN
4 DR. FRIEDMAN AND THEN JEFF SHEEHY.

5 DR. STEWARD: THANK YOU. THIS HAS BEEN, I
6 THINK, A VERY IMPORTANT CONCEPT COMING FORWARD.
7 IT'S PROBABLY ONE OF THE MOST IMPORTANT THINGS THAT
8 WE'RE SEEING, AND I WANT TO CONGRATULATE YOU ON
9 REALLY A VERY CAREFUL AND THOUGHTFUL PLAN HERE.

10 THERE ARE A COUPLE OF THINGS THAT DO WORRY
11 ME JUST A LITTLE BIT, AND I'LL EXPRESS THOSE. AND
12 IT MAINLY HAS TO DO WITH THE LIMITS AND THE DANGER
13 OF LOSING SOMETHING REALLY GOOD BECAUSE OF THOSE
14 LIMITS. SO AN EXAMPLE MIGHT BE THE SPECIFIC DATES
15 OF THE PROPOSAL. I THINK THERE'S AN EASY FIX FOR
16 THIS. FOR EXAMPLE, IF SOMEBODY WAS ABLE TO COME IN
17 WITH AN IND FILING A WEEK AFTER THE DEADLINE FOR THE
18 GRANT SUBMISSION, WOULDN'T THAT BE A PITY IF THAT
19 WAS THE ONE THAT WAS REALLY THE HOME RUN?

20 I WONDER IF THERE'S A WAY TO DO A ROLLING
21 APPLICATION PROCESS INSTEAD OF A SINGLE APPLICATION
22 PROCESS. WE WOULD HAVE A LITTLE BIT OF A SPAN HERE.

23 DR. TROUNSON: WE COVERED TO SOME EXTENT
24 UNDER THE SUP- -- FOR THEM TO BE ABLE TO PROVIDE US
25 SUPPLEMENTAL MATERIAL UP UNTIL THE CONSIDERATION BY

BARRISTERS' REPORTING SERVICE

1 THE GRANTS REVIEW TEAM. I THINK YOU HAVE TO
2 PROBABLY HAVE AN IND FILED IN PLACE BY THAT STAGE.
3 OTHERWISE YOU'RE MOST UNLIKELY TO HAVE IT A LITTLE
4 FURTHER ON. BUT WE'RE NOT AWARE OF ANYONE THAT
5 MIGHT BE IN THAT STATE. AS I SAID, PERHAPS IT COULD
6 HAPPEN, BUT AT LEAST UP UNTIL THE ACTUAL TIME THAT
7 THE GRANT REVIEW TEAM WOULD EXAMINE THE PROPOSALS,
8 THEY'RE ABLE TO BRING FORWARD.

9 DR. STEWARD: WHAT I'M REALLY ASKING IS
10 WOULD IT BE POSSIBLE TO HAVE A COUPLE OF DIFFERENT
11 TIMES WHERE THE GRANT REVIEW TEAM COULD EXAMINE THE
12 PROPOSALS.

13 DR. OLSON: I DO WANT TO POINT OUT THAT
14 THE -- YOU KNOW, THE DISEASE TEAM II WOULD ALSO
15 ENCOMPASS THIS SPACE, WILL BE COMING A FEW MONTHS
16 LATER; AND DEPENDING ON HOW WE, SAY, FIX THE
17 PRIORITIES, I MEAN JUST SAY THERE'S A PROGRAMMATIC
18 INTEREST IN PLURIPOTENT STEM CELLS, BUT I THINK THAT
19 ONE WOULD BE BROADER. IN OTHER WORDS, ANYBODY COULD
20 COME IN FOR THAT. CERTAINLY A PLURIPOTENT
21 CELL-DERIVED THERAPY WOULD NOT BE RESTRICTED FROM
22 THAT ONE SEEING AS THAT ONE'S REALLY QUITE CORE TO
23 OUR MISSION AND TO THAT PARTICULAR STRATEGIC GOAL.

24 SO I THINK BOTH THE SUPPLEMENTAL DATA
25 POLICY AS WELL AS THE TIMING OF THE SUBSEQUENT

BARRISTERS' REPORTING SERVICE

1 DISEASE TEAM II RFA WOULD ADDRESS BOTH OF YOUR
2 CONCERNS.

3 CHAIRMAN KLEIN: DR. STEWARD, I THINK WE
4 HAVE A CLARIFICATION EFFECTIVELY FOR THE RECORD THAT
5 DR. TROUNSON HAS MADE, THAT THE IND WOULD NEED TO BE
6 IN PLACE -- THE FILING WOULD NEED TO BE IN PLACE BY
7 THE GRANT REVIEW AS VERSUS THE SUBMISSION OF THE
8 GRANT.

9 DR. STEWARD: THAT HELPS.

10 DR. OLSON: THREE WEEKS BEFORE.

11 DR. STEWARD: IF I COULD JUST ASK ANOTHER
12 QUESTION. AGAIN, IT SORT OF RELATES TO THIS ISSUE
13 OF CUTTING OUR SAMPLE TOO SHORT. WE'VE SEEN THAT
14 SOME THINGS HAVE GONE FORWARD AND ACTUALLY GOTTEN
15 FDA APPROVAL AND THEN BEEN PUT ON CLINICAL HOLD.
16 THE TIMING OF THAT, NONE HAVE BEEN RELEASED, SO WE
17 DON'T KNOW HOW LONG THAT PROCESS IS GOING TO TAKE
18 FOR ANY OF THE PROJECTS UNDER WAY NOW OR FOR
19 PROJECTS IN THE FUTURE. IS THERE SOMETHING BUILT IN
20 THAT WILL --

21 DR. OLSON: YES. THE MECHANISM THAT'S
22 BUILT IN TO DEAL WITH THAT -- AS YOU RIGHTLY POINT
23 OUT, THE ONES THAT WE ARE AWARE OF THAT HAVE FILED
24 IND'S IN THIS SPACE ARE ON CLINICAL HOLD CURRENTLY.
25 BUT WHAT WOULD HAPPEN IS WE WOULD REQUIRE AN ACTIVE

BARRISTERS' REPORTING SERVICE

1 IND AT THE NOTICE OF AWARD. TYPICALLY WE ASK THAT
2 PEOPLE INITIATE THEIR PROGRAMS; THAT IS, THE NOTICE
3 OF AWARD BE ISSUED WITHIN SIX MONTHS OF THE DECISION
4 BY THIS BOARD TO FUND. SO THAT ALREADY PUTS YOU,
5 YOU HAVE NOW FROM APPLICATION DEADLINE WHEN YOU
6 FILED YOUR IND TO ARGUABLY SIX MONTHS AFTER THE
7 BOARD HAS APPROVED AN APPLICATION.

8 AND THERE'S ALSO IF -- THEY CAN APPLY FOR
9 SPECIAL CONSIDERATION TO THE PRESIDENT TO EXTEND
10 THAT SIX-MONTH DEADLINE. SO THERE IS A MECHANISM IN
11 PLACE TO ADDRESS THE FACT THAT, YOU KNOW, IT'S VERY
12 HARD TO PREDICT WHEN A HOLD WILL BE LIFTED, BUT
13 THAT'S HOW WE WORK WITH THAT.

14 CHAIRMAN KLEIN: THANK YOU. I THINK WE
15 HAVE DR. TROUNSON.

16 DR. TROUNSON: I THINK THEY ARE GOOD
17 QUESTIONS, OS. IN DOING THIS AT THE TIME WITH THE
18 DISEASE TEAM FOLLOWING UP, YOU KNOW, I AM CONCERNED
19 ABOUT TRYING TO GET ONTO THE FRONT FOOT FOR OUR
20 MISSION BECAUSE WE'RE MEANT TO HAVE A PLURIPOTENTIAL
21 STEM CELL INITIATIVE THROUGH THAT II A, II B PROCESS
22 IN TIME, AND TIME'S PASSING. SO THEY DON'T ALL MAKE
23 IT. SO THERE'S SOME SENSE OF URGENCY TO SORT OF
24 HELP THOSE THAT ARE NEAR THE FRONT LINE IF WE'RE
25 GOING TO MEET OUR MISSION TARGETS. BRINGING THE

BARRISTERS' REPORTING SERVICE

1 OTHERS THROUGH BEHIND, WE MAY NOT MEET OUR MISSION.
2 BUT IF WE'VE GOT SOME OF THE FRONT LINE AND IF THEY
3 MAKE IT, OF COURSE, THEN WE'RE ABLE TO CEMENT IN
4 SOME OF THE KEY MISSION OBJECTIVES.

5 AND HOPEFULLY, IMPORTANTLY, I THINK IN
6 DOING THAT WE WILL LEARN SO MUCH FROM THESE PEOPLE
7 IN THE FRONT LINE ABOUT HOW TO HELP THOSE PEOPLE
8 COMING BEHIND. AND THAT WILL BE -- GETTING THAT
9 INFORMATION FROM WHAT IS REQUIRED TO GET THROUGH
10 THIS RATHER DIFFICULT PATHWAY, BECAUSE IT HASN'T
11 BEEN TRAVELED REALLY BY ANYONE, IS SO CRITICAL FOR
12 US TO HELP THE UP-AND-COMING PROGRAMS THAT ARE A
13 LITTLE FURTHER BACK.

14 CHAIRMAN KLEIN: THANK YOU. DR. FRIEDMAN.

15 DR. FRIEDMAN: I THINK THIS IS A VERY GOOD
16 IDEA. AND MY ONLY QUESTION AND CONCERN REALLY IS
17 ABOUT THE TIMING. YOU SAY THAT THERE ARE RELATIVELY
18 FEW THAT YOU KNOW OF. AND WHILE YOU DON'T KNOW OF
19 ALL OF THEM, YOU KNOW OF MANY OF THEM ANYWAY. I
20 THINK THAT IF WE WEREN'T GOING TO HAVE THE DISEASE
21 TEAM II COMING UP JUST BEHIND IT, I WOULDN'T BE
22 MAKING THE SUGGESTION TO YOU THAT WE CONSIDER
23 DELAYING THIS BY A YEAR.

24 MY RATIONALE GOES SOMETHING LIKE THIS.
25 EVERYTHING THAT YOU HOPE TO DO WITH THIS YOU COULD

BARRISTERS' REPORTING SERVICE

1 SWEEP INTO DISEASE TEAM II. AND SINCE WE KNOW THERE
2 ARE RELATIVELY FEW CANDIDATES, BY SIGNALING TO THE
3 GENERAL COMMUNITY, BOTH ACADEMIC AND INDUSTRIAL, THE
4 INTENTION TO DO THIS, YOU REALLY GIVE PEOPLE A
5 TARGET TO SHOOT FOR. I TAKE, OS, YOUR POINT ABOUT
6 TIMING IS TOUGH. I DON'T SEE HOW YOU CAN HAVE A
7 ROLLING SET OF REVIEWS. ALTHOUGH IT'S VERY
8 ATTRACTIVE, I THINK WE JUST DON'T HAVE ENOUGH MONEY
9 TO DO IT.

10 YOU POINT OUT THAT THESE ARE HIGH RISK.
11 THAT DOESN'T MEAN I'M DISINTERESTED. IT MEANS I
12 ACTUALLY LIKE IT. BUT IT DOES MEAN THAT I WOULD
13 LIKE TO HAVE THE LARGEST NUMBER OF CREATIVE
14 APPLICATIONS READY TO GO. SO I'M VERY SUPPORTIVE OF
15 THIS, BUT I PERSONALLY HAVE RESERVATIONS ABOUT DOING
16 IT RIGHT NOW AND THINK THAT ANOTHER YEAR OF
17 MATURATION WILL MEAN THAT THE POOL OF CANDIDATES TO
18 COMPETE FOR THIS, I CAN'T PROMISE YOU IT WILL BE
19 BETTER, BUT I SUSPECT THAT IT'S LIKELY TO BE VERY
20 MUCH BETTER.

21 CHAIRMAN KLEIN: SO, DR. FRIEDMAN, I THINK
22 DR. TROUNSON'S SIGNAL POINT HERE IS THAT BY FUNDING
23 SOME LEAD CANDIDATES, WE EDUCATE THE ENTIRE POOL TO
24 FOLLOW, AND THAT THAT LEAD CANDIDATE FUNCTION OF
25 EXPLORING THE OBSTACLES AND GIVING US EARLY

BARRISTERS' REPORTING SERVICE

1 INFORMATION OF WHERE THOSE OBSTACLE ARE MAY INFORM
2 ADDITIONAL BASIC RESEARCH WE NEED TO HAVE AS
3 COMPLEMENTARY OR TRANSLATIONAL COMPLEMENTARY
4 RESEARCH.

5 DR. FRIEDMAN: I DO APPRECIATE THAT FACT.
6 OF COURSE, THAT MAY WELL BE TRUE. MY CONCERN,
7 THOUGH, IS THAT FROM A REGULATORY POINT OF VIEW, THE
8 REGULATORS MAY SIMPLY SAY WHEN YOU'VE SEEN ONE IND,
9 YOU'VE SEEN ONE IND. AND I'M NOT SURE HOW MUCH IS
10 GOING TO BE TRANSFERABLE FROM ONE TO THE NEXT. I
11 COULD BE VERY WRONG ABOUT THAT. I THINK IT'S A
12 VALID POINT YOU ARE MAKING. I'M NOT SO CONVINCED BY
13 IT, BUT, YOU KNOW, WE WON'T KNOW.

14 DR. TROUNSON: I THINK THERE ARE TWO
15 POINTS THAT I'D LIKE TO MAKE IN RESPONSE, MICHAEL.
16 ONE IS I'M AWARE OF TWO OF THESE ENTITIES MAY NOT BE
17 ABLE TO CONTINUE, AND THAT WOULD MEAN THAT THEY GOT
18 THERE AND THEY FELL BACKWARDS. NOW, WHETHER THAT'S
19 TRUE OR NOT, I'M NOT A FINANCIAL ANALYST OF ANY
20 KIND. BUT THERE ARE WARNING SIGNS THAT WITHOUT SOME
21 ASSISTANCE, SO THEY'RE GOING FIND IT REALLY, REALLY
22 HARD. NO. 1, I DON'T WANT TO LOSE THAT IF IT'S AN
23 EDGE JUST TO HELP.

24 SECONDLY, I THINK IN TERMS OF SOME OF THE
25 MANUFACTURING AND SOME OF THE CELL CHARACTERISTIC

BARRISTERS' REPORTING SERVICE

1 ISSUES, THERE HAVE BEEN SOME SURPRISES BY THE
2 FRONTLINE GROUPS IN HAVING TO DEMONSTRATE SOME
3 PARTICULAR CHARACTERISTICS, AS YOU MIGHT IMAGINE.
4 AND THEY HAVE BEEN HELPED ACROSS THE LINE BY HAVING
5 TO ADDRESS THOSE, AND THEY'RE CLEARLY WILLING, AT
6 LEAST IN DISCUSSION WITH ME, THAT IF THEY'RE ABLE TO
7 BE AWARDED, THAT THEY WOULD HELP IN THESE REGARDS.
8 AND SO I DO THINK THAT THEY'VE GOT SOME SPECIFIC
9 INFORMATION THAT'S NOT CURRENTLY PUBLIC.

10 DR. FRIEDMAN: EXPLAIN TO US, THEN, WHY
11 THIS WOULDN'T BE CAPTURED UNDER THE DISEASE TEAM
12 RESEARCH II.

13 DR. TROUNSON: IT COULD BE CAPTURED UNDER
14 THAT, BUT IT WOULD BE SIGNIFICANTLY LATER. AND I'M
15 CONCERNED ABOUT THE NEED TO DO IT EARLIER RATHER
16 THAN LATER. THE LATER ONE WITH THE DISEASE TEAMS,
17 OF COURSE, WILL, I IMAGINE, PROBABLY BE A WIDER
18 BRIEF THAN PLURIPOTENTIALITY. BUT I'M A LITTLE
19 CONCERNED ABOUT THE HEALTH OF THESE ENTITIES THAT
20 ARE UP THERE AT THE MOMENT, AND THEY MAY NOT, FOR
21 EXAMPLE, BE ABLE TO SURVIVE A LONG TIME WITHOUT SOME
22 SUPPORT.

23 CHAIRMAN KLEIN: JEFF SHEEHY.

24 MR. SHEEHY: I'M GOING TO TAKE THE EXACT
25 OPPOSITE TACK OF DR. FRIEDMAN. I JUST WANT TO SAY

BARRISTERS' REPORTING SERVICE

1 HOW IMPRESSED I AM WITH DR. OLSON, DR. TROUNSON, AND
2 STAFF. THIS IS WHAT PATIENT ADVOCATES HAVE BEEN
3 PLEADING FOR. AND THE WAY IN WHICH THEY PUT THIS
4 TOGETHER, I KNOW WHAT THEIR SCHEDULE LOOKS LIKE FOR
5 THE REST OF THE YEAR BECAUSE I'M GOING TO BE AT
6 THOSE REVIEW MEETINGS. I'M WONDERING HOW I'M GOING
7 TO GET THERE. SO I AM SO PROUD OF OUR TEAM, AND I'M
8 SO PROUD OF THE WORK THEY'VE DONE. AND THIS
9 AGGRESSIVENESS, THIS URGENCY IS EXACTLY WHAT WE NEED
10 TO DO.

11 SO I HAD TWO QUESTIONS. AND ONE IS JUST
12 CLARIFICATION. THIS IS JUST ME. I DIDN'T REALLY
13 UNDERSTAND WHAT YOU MEANT BY PIVOTAL. I'M SURE FOR
14 A LOT OF FOLKS THAT WAS JUST SELF-EVIDENT. AND I
15 JUST WANTED TO HAVE A SENSE, ALMOST LIKE A
16 DEFINITION BECAUSE I KNOW PHASE I, PHASE II, PHASE
17 III.

18 DR. OLSON: PIVOTAL IS STATISTICALLY --
19 IT'S TYPICALLY A PHASE III, BUT SOMETIMES IT CAN BE,
20 IN CERTAIN ONCOLOGY INDICATIONS OR IN SOME
21 CIRCUMSTANCES, IT CAN BE A PHASE II. BASICALLY IT'S
22 A STUDY THAT MEETS AN END POINT THAT'S AGREED TO
23 WITH THE FDA THAT SHOWS BENEFIT TO PATIENTS. SO
24 IT'S AN EFFICACY END POINT THAT'S ACCEPTED IN ENOUGH
25 PATIENTS.

BARRISTERS' REPORTING SERVICE

1 IT'S THE BASIS FOR MARKETING APPROVAL.

2 CHAIRMAN KLEIN: THAT DOES NOT ELIMINATE
3 FUNDING PHASE II A STUDIES FOR PRELIMINARY EFFICACY.

4 DR. OLSON: NO. I'M CLASSIFYING PHASE
5 II A STUDIES WITH PRELIMINARY INDICATIONS OF
6 EFFICACY WITHIN THE CONTEXT OF THE SCOPE OF THIS
7 RFA.

8 MR. SHEEHY: THAT MAKES PERFECT SENSE. I
9 KNOW WHAT IT MEANS TO FUND MOST OF THOSE STUDIES. I
10 THINK THAT'S NOT WITHIN OUR REALM. AGAIN, NOT TO
11 PUT ANYTHING ELSE ON YOU GUYS BECAUSE I AM SO
12 IMPRESSED. I REALLY HAVE THIS INCREDIBLE SENSE OF
13 PRIDE IN OUR SCIENTIFIC TEAM IN TAKING ON THIS
14 CHALLENGE.

15 AS WE LEARN ABOUT THIS, I HOPE THAT WE
16 CAN -- I'M TALKING ABOUT A YEAR FROM NOW -- SOME
17 MECHANISM TO LINK THIS TO THE DISEASE TEAMS THAT WE
18 HAVE ONGOING IF THEY HAPPEN TO REACH AN IND. SO IF
19 THERE'S SOME SYNCHRONICITY SO THAT, YOU KNOW, MAYBE
20 THEY HAVE SOME MONEY LEFT OVER, MAYBE THAT CAN APPLY
21 TO SOME -- JUST SOMETHING SO THAT WE CAN BE REALLY
22 SEAMLESS. BUT, AGAIN, I JUST THINK THIS IS
23 SPECTACULAR AND THANK YOU.

24 DR. OLSON: THANK YOU. WE'RE ALREADY
25 THINKING THAT WAY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SO, DR. PRIETO, DID YOU
2 HAVE A COMMENT?

3 DR. PRIETO: TO MAKE A MOTION ACCEPTING
4 THIS CONCEPT PROPOSAL FOR AN RFA.

5 CHAIRMAN KLEIN: IF YOU COULD MAKE A
6 MOTION, THEN I'M GOING TO WALK ON TO ADDITIONAL
7 BOARD COMMENT.

8 DR. PRIETO: SO MOVED.

9 CHAIRMAN KLEIN: SO THERE'S A MOVE. FOR
10 THE TRANSCRIPTION THAT'S BEING MADE ON THE AUDIO
11 FILE, WOULD YOU PLEASE IDENTIFY WHO THE SECOND IS?

12 DR. LOVE: TED LOVE.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH. DR.
14 PULIAFITO, I BELIEVE YOU HAD A COMMENT.

15 DR. PULIAFITO: CAN YOU GIVE US A SENSE OF
16 THE KIND OF PROPOSALS THAT YOU SEE OUT THERE THAT
17 MIGHT MEET ALL THE CONSTRAINTS OF THIS REQUEST?

18 DR. TROUNSON: THERE'S A RATHER SMALL
19 NUMBER OF THEM, SO I'M HESITANT.

20 CHAIRMAN KLEIN: IT'S BETTER FOR PURPOSES
21 OF CONFLICTS AND OTHER ISSUES THAT WE NOT IDENTIFY
22 THOSE SPECIFICALLY BECAUSE THEN WE'D HAVE TO DO A
23 CONFLICTS CLEARANCE.

24 DR. PULIAFITO: THAT'S MY POINT EXACTLY.
25 WHAT I'M CONCERNED ABOUT IS, AS I LOOK AT THE

BARRISTERS' REPORTING SERVICE

1 CONSTRAINTS, THE UNIVERSE OF POSSIBLE APPLICATIONS
2 WILL BE RATHER SMALL. SO I'M CONCERNED THAT WE'RE
3 NOT -- THAT WE MAY BE FAVORING THESE EARLY
4 INDIVIDUALS WITHOUT HAVING, WHAT DR. FRIEDMAN SAID,
5 MORE TIME TO HAVE BROADER PROPOSALS. WHAT I'M
6 CONCERNED ABOUT IS ARE WE REALLY LOOKING AT AN
7 EARMARK OF MONEY FOR THESE?

8 CHAIRMAN KLEIN: NO, WE'RE NOT. WHAT
9 WE'RE DOING HERE IS, WHILE ANECDOTALLY THE PRESIDENT
10 IS AWARE OF A FEW CASES, WHICH HE CAN VET TO TRY AND
11 MAKE SURE THAT THERE'S A REAL NEED THERE, AS DR.
12 TROUNSON INDICATED, THERE MAY BE A SIGNIFICANTLY
13 GREATER NUMBER WHO ACTUALLY APPLY. IN FACT, I HAVE
14 A COMMENT LATER TO ADDRESS AN ADDITIONAL SUBCATEGORY
15 HERE. BUT, AGAIN, THIS IS TO TRY AND CREATE A LEAD
16 GROUP OF CANDIDATES THAT HELP EDUCATE ALL OF US.

17 DR. OLSON.

18 DR. OLSON: I JUST WANT TO MAKE ONE POINT.
19 IN CLINICAL DEVELOPMENT IT IS GOING TO BE IMPORTANT
20 TO HAVE A PIPELINE OF PROGRAMS. WE ARE GOING TO
21 HAVE TO ROUTINELY -- WE WERE GOING TO REPEAT A
22 DISEASE TEAM EVERY YEAR. THAT DISEASE TEAM, AS
23 WE'RE CURRENTLY THINKING OF IT, WILL INCLUDE
24 PROGRAMS WHERE AN END POINT MIGHT BE ENROLLING THE
25 FIRST PATIENTS, SO IT WOULD INCLUDE THE PRECLINICAL

BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT PHASE AND FILING THE IND. IT COULD HAVE
2 AN END POINT OF A PHASE II A. THAT COULD BE ANOTHER
3 END POINT FOR IT. SO IT COULD CAPTURE IN A BUNCH --
4 IN SEVERAL AREAS.

5 BUT WE NEED TO BE ABLE TO PICK UP PEOPLE
6 WHEN THEY ARE READY. AND, THEREFORE, IT IS
7 IMPORTANT TO HAVE A REPEATING TYPE OF RFA OF THIS
8 NATURE, WHETHER IT BE DISEASE TEAM OR THIS ONE THAT
9 IS SPECIFICALLY TARGETED TO AN ASPIRATIONAL
10 OBJECTIVE THAT WE HAVE, AND TO PICK UP PEOPLE AS
11 THEY COME ALONG.

12 CHAIRMAN KLEIN: AND SO, DR. PULIAFITO,
13 I'D ALSO REMIND YOU THAT THE BOARD HAS ALREADY ASKED
14 THE STAFF TO COME BACK IN TERMS OF DISEASE TEAM I
15 WHERE THE RESEARCH GOES FASTER THAN ANTICIPATED AND
16 WHERE THEY HAVE LEFTOVER FUNDS FOR RECOMMENDATIONS
17 ON HOW WE CAN MODIFY DISEASE TEAM I'S SO CARRY-OVER
18 FUNDS COULD BE USED TO BEGIN A PHASE I TRIAL. SO
19 WE'RE GOING TO HAVE A NUMBER OF PROGRAMS AND
20 MODIFIED PROGRAMS AS WE GO TO TRY AND BROADEN THIS
21 FIELD. THIS IS AN INITIAL STEP.

22 DR. PULIAFITO: IS IT REASONABLE, AS DR.
23 STEWARD SUGGESTED, TO HAVE THIS AS A ROLLING PROCESS
24 OR NOT REALLY?

25 DR. TROUNSON: I THINK WE'RE GOING TO PICK

BARRISTERS' REPORTING SERVICE

1 THAT UP IN THE DISEASE TEAMS. YOU CAN ARGUE THAT --
2 YOU MIGHT ARGUE, AND IT MIGHT BE WORTH DISCUSSING
3 THAT AT SOME POINT, THAT THE PLURIPOTENTIAL STEM
4 CELLS IN COMPETITION WITH EVERYTHING ELSE MIGHT
5 REALLY BE CHALLENGED. BUT THEY SEEM TO HAVE BEHAVED
6 COMPETITIVELY RATHER WELL UP UNTIL NOW. I THINK
7 IT'S REASONABLE. BUT SO I THINK DISEASE TEAMS CAN
8 ACCOMMODATE THAT SCOPE BECAUSE WE'VE PUSHED
9 TRANSLATION UP A BIT AND WE'VE GOT THE DISEASE TEAMS
10 IN PROCESS PHASE. WE WANT TO TRY AND DO THEM, THE
11 DISEASE TEAMS, EVERY 12 OR AT THE MOST 15 MONTHS,
12 BUT GET THEM INTO THAT FRAMEWORK. I THINK WE CAN
13 HANDLE IT.

14 AGAIN, MY VIEW, YOU EMPLOYED ME TO GET YOU
15 THE MISSION. I NEED THIS TO HELP DELIVER ON IT IN
16 MY OWN VIEW. SO THAT'S WHY THE STAFF ARE PUTTING
17 THIS IN A VERY POSITIVE WAY. I THINK IT IS A
18 POSSIBILITY THAT WE GET NONE, THAT THEY MAY NOT PASS
19 MUSTER, WHATEVER. YOU TAKE THAT RISK, BUT I THINK
20 WE'VE GOT GO OUT THERE AND SEE WHO'S READY TO GO ON
21 THIS. WE KNOW THAT THERE ARE SOME PEOPLE OUT THERE
22 SUFFERING A BIT UP AT THAT FRONT LINE, SO I THINK IT
23 IS THE RIGHT TIME.

24 CHAIRMAN KLEIN: SO WE HAVE DR. HAWGOOD,
25 DR. FONTANA, WE HAVE SHERRY LANSING, AND WE HAVE

BARRISTERS' REPORTING SERVICE

1 JEFF SHEEHY. TED LOVE ACTUALLY, SHERRY, HAS ASKED
2 PREVIOUSLY. I SKIPPED OVER HIM. DR. HAWGOOD, DR.
3 FONTANA, DR. LOVE, SHERRY LANSING, AND JEFF SHEEHY.
4 WE HAVE AN ENGAGED BOARD HERE.

5 MS. SAMUELSON: AND JOAN SAMUELSON.

6 CHAIRMAN KLEIN: JOAN, YOU'RE ON THE LIST.
7 WE WILL CALL YOU IN THAT ORDER.

8 DR. HAWGOOD: QUESTION IS ABOUT TIMING,
9 BUT NOT WHEN THE GRANTS GET STARTED, BUT THE
10 DURATION. THREE YEARS SOUNDS AGGRESSIVE TO GET A
11 TRIAL OF THIS COMPLEXITY GOING, AND MORE IMPORTANTLY
12 BECAUSE SAFETY IS GOING TO BE ONE OF THE KEY ISSUES.
13 I HOPE THERE'S A MECHANISM FOR CONTINUED FOLLOW-UP
14 SO THAT WE DON'T FIND SOMETHING FIVE YEARS DOWN THE
15 LINE THAT WE DON'T JUST DECLARE SUCCESS AT THREE
16 YEARS. WE'LL HAVE TO HAVE SOME FUNDING MECHANISM TO
17 ALLOW FOLLOW-UP.

18 DR. TROUNSON: SAM, I HAVE TALKED TO THE
19 PEOPLE THAT ARE IN THIS SPACE. THEY BELIEVE A
20 THREE-YEAR TIME PROGRAM IS APPROPRIATE.

21 DR. HAWGOOD: TO ENROLL PATIENTS, BUT I
22 THINK THERE'S GOING TO BE A NEED TO FOLLOW THEM.

23 DR. TROUNSON: A LOT OF THIS WILL BE IN
24 PHASE I CLEARLY AND THEN PHASE II A. USUALLY THE
25 PHASE II A IS NOT A LARGE NUMBER OF PATIENTS. AND

BARRISTERS' REPORTING SERVICE

1 IF YOU GET PHASE I TO BE ACCEPTABLE, THEN YOU
2 GENERALLY, GENERALLY CAN MOVE ON TO PHASE II, AND
3 YOU OBVIOUSLY GET A BIG RESPONSE BY THE PATIENTS IF
4 A PHASE I HAS BEEN SUCCESSFUL.

5 SO I UNDERSTAND THAT IN SOME OF THESE
6 INDICATIONS MAYBE YOU'D WANT TO LOOK OVER A TEN-YEAR
7 TIMEFRAME; BUT, AGAIN, I THINK THE PATIENTS HAVE TO
8 BE -- PATIENT'S WILL AND THEIR NEED NEEDS TO BE
9 RESPECTED WITHIN THIS. AND, OF COURSE, THE FDA ARE
10 A NATURALLY CAUTIOUS GROUP OF PEOPLE. AND SO WE
11 WILL STAY LINKED WITH THAT, OF COURSE, AND THEY
12 CAN'T MOVE MORE QUICKLY THAN FDA WILL ALLOW.

13 CHAIRMAN KLEIN: WE'RE GOING TO MOVE TO
14 DR. FONTANA. AND REMEMBER THE COMMENT, IF WE ADOPT
15 THIS, DR. HAWGOOD, WITH THE PROVISION GIVING THE
16 PRESIDENT ABILITY TO ADJUST THE TECHNICAL TO FOLLOW
17 OUR SUBSTANTIVE INTENT, THEN HE CAN ADAPT IF WE NEED
18 THREE AND A HALF YEARS OR FOUR YEARS FOR A
19 PARTICULARLY MERITORIOUS AWARD.

20 DR. FONTANA.

21 DR. FONTANA: I'M ALSO AGREEING WITH THE
22 COMMENTS THAT I THINK THIS IS A GREAT PROGRAM AND
23 VERY SUPPORTIVE OF IT. I JUST WANTED SOME
24 CLARIFICATION. HOW ARE YOU GOING TO DEAL WITH THE
25 COMPANIES THAT HAVE THE IND THAT ARE OUTSIDE OF THE

BARRISTERS' REPORTING SERVICE

1 STATE?

2 DR. OLSON: THEY WILL HAVE TO -- CIRM CAN
3 ONLY FUND RESEARCH CONDUCTED IN CALIFORNIA.

4 DR. FONTANA: THE WORK CAN BE DONE IN THE
5 STATE, IN CALIFORNIA, EVEN THOUGH THE PARENT COMPANY
6 CAN BE OUTSIDE.

7 DR. OLSON: I WILL -- I WOULD HAVE TO
8 CHECK WITH OUR ATTORNEY ON THAT, BUT I BELIEVE IF
9 THE WORK IS CONDUCTED IN CALIFORNIA AND IF THE
10 COMPANY --

11 CHAIRMAN KLEIN: DR. OLSON IS CORRECT. IF
12 THE WORK IS DONE IN CALIFORNIA, THE COMPANY CAN BE
13 FROM OUTSIDE OF CALIFORNIA, AND WORK UNDER MATCHING
14 FUNDS CAN BE DONE OUTSIDE OF CALIFORNIA. IT'S OUR
15 FUNDS THAT HAVE TO BE EXPENDED IN CALIFORNIA.

16 DR. FONTANA: ANOTHER CLARIFICATION. YOU
17 SAID CIRM FUNDING, THE WORK HAD TO BE DONE IN
18 CALIFORNIA; BUT IF THEY HAVE MATCHING FUNDS AND
19 RUNNING TRIALS PERHAPS OUTSIDE THE STATE, WHICH I
20 THINK IS GREAT.

21 DR. OLSON: THAT'S PART OF THE PROGRAM.

22 DR. FONTANA: I THINK IT'S WONDERFUL.

23 CHAIRMAN KLEIN: THANK YOU VERY MUCH. DR.
24 LOVE.

25 DR. LOVE: I WAS JUST GOING TO MAKE THREE

BARRISTERS' REPORTING SERVICE

1 QUICK POINTS. ONE IS I THINK -- I THOUGHT THROUGH
2 SOME OF THE CONCERNS THAT DR. FRIEDMAN AND, CARMEN,
3 THAT YOU MADE; BUT WHEN I KIND OF SYNTHESIZED IT
4 ALL, I CAME TO THE CONCLUSION THAT I THINK JEANNIE
5 JUST ARTICULATED, WHICH I THINK THIS IS A BRILLIANT
6 PROGRAM PARTICULARLY WHEN YOU THINK ABOUT THE
7 SPOTLIGHT THAT WE HAD THIS MORNING AND THE MISSION
8 HERE. WE DON'T, I THINK, HAVE THE LUXURY OF WAITING
9 FOR TEN PROGRAMS TO GET TO A CERTAIN LEVEL BEFORE WE
10 FUND THE FIRST ONE THAT WE THINK IS MERITORIOUS.

11 AND THE SECOND POINT I WAS GOING TO MAKE
12 IS THAT I THINK THAT IN PARTICIPATING IN THESE
13 PROCESSES BEFORE, THIS GROUP ISN'T GOING TO FUND
14 ANYTHING WHICH ISN'T OF QUALITY. SO IF WE GET ONE
15 APPLICANT AND WE DON'T THINK IT'S QUALITY, WE WON'T
16 FUND IT. I DON'T THINK THAT CONCERN REALLY IS
17 SOMETHING THAT WE HAVE TO WORRY ABOUT.

18 FINALLY, I WAS JUST GOING TO SAY, PAT, I
19 THINK YOU AND YOUR TEAM DID A REALLY ELEGANT JOB OF
20 THINKING IT THROUGH AND LAYING IT OUT AND PRESENTING
21 IT. SO THANK YOU.

22 CHAIRMAN KLEIN: THANK YOU, DR. LOVE.
23 SHERRY AND THEN JEFF AND THEN JOAN.

24 MS. LANSING: IRONICALLY THE TWO L'S, YOU
25 PRETTY MUCH SAID WHAT I WAS GOING TO SAY. SO I WILL

BARRISTERS' REPORTING SERVICE

1 BE VERY BRIEF IN CONGRATULATING YOU ON THE WORK AND
2 ALSO SAYING THIS IS WHAT WE ARE ALL SUPPOSED TO BE
3 ABOUT, WHICH IS GETTING TO THE PATIENTS.

4 AND THE REASON THAT I'M NOT THE LEAST BIT
5 NERVOUS ABOUT IT, WHETHER WE HAVE ONE APPLICANT OR
6 THREE APPLICANTS OR 20 APPLICANTS, IS YOU DON'T HAVE
7 TO SPEND THE MONEY. SO I AM ASSUMING THAT IF WE DO
8 NOT HAVE A SINGLE GOOD APPLICANT, YOU WILL COME BACK
9 TO US AND SAY WE'RE GOING TO DO ANOTHER ONE IN SIX
10 MONTHS OR A YEAR, WHATEVER IT IS. I AM NOT ASSUMING
11 YOU ARE GOING TO SPEND THE ENTIRE AMOUNT UNLESS YOU
12 SEE THINGS THAT ARE GREAT. AND WE NEVER HAVE
13 BEFORE, SO I HAVE NO CONCERN ABOUT IT. I THINK IT'S
14 GOOD TO GET THE PROGRAM GOING, AND I WILL NOT
15 CONSIDER IT A FAILURE IF YOU DON'T SPEND THE MONEY,
16 AND I'LL BE HAPPY IF YOU DO BECAUSE THAT MEANS
17 THERE'S GREAT STUFF. SO I LEAVE IT IN YOUR
18 JUDGMENT.

19 MR. SHEEHY: I WANT TO JUST REITERATE
20 THOSE OTHER COUPLE OF POINTS, JUST NOT TO OVERHIT
21 THIS, BUT, YOU KNOW, REALLY LET'S LOOK AT THE KEY
22 CONTROL MECHANISM IN TERMS OF ADVICE THAT WE GET ON
23 GRANTS. THIS GRANTS WORKING GROUP IS A TOUGH-NOSED
24 GROUP, AND THEY ARE NOT SPENDING OUR MONEY ANYWHERE
25 NEAR THE WAY I WOULD SPEND IT. I WOULD BE WRITING

BARRISTERS' REPORTING SERVICE

1 CHECKS A LOT MORE. THEY ARE VERY SERIOUS, THEY'RE
2 SOBER, THEY'RE DELIBERATE. AND AS WE SAW IN THE
3 DISEASE TEAMS, THEY WERE VERY CONSERVATIVE IN WHAT
4 THEY RECOMMENDED.

5 I THINK WE HAVE SOME OUTSTANDING PHYSICIAN
6 SCIENTISTS, WE HAVE SOME OUTSTANDING RESEARCHERS,
7 CLINICAL SCIENTISTS. AND I HAVE NOT SEEN ANY
8 EVIDENCE THAT THEY WOULD PUT FORWARD SOMETHING IN A
9 RECKLESS OR NOT IN THE MOST SCIENTIFIC -- I MEAN THE
10 RIGOR OF OUR REVIEW IS SO HIGH. THE INDEPENDENCE,
11 BECAUSE NONE OF THESE FOLKS CAN COMPETE FOR OUR
12 GRANTS, IS SO HIGH, THAT EVEN IF WE JUST HAD ONE
13 APPLICATION AND WE WERE HELL BENT ON SPENDING THAT
14 MONEY, THERE'S NO WAY WE COULD GET A POSITIVE
15 RECOMMENDATION FROM THEM IF THE SCIENCE WASN'T THERE
16 TO DO SO.

17 CHAIRMAN KLEIN: JOAN. JOAN SAMUELSON,
18 CAN YOU HEAR ME?

19 MS. SAMUELSON: YES, I CAN. CAN YOU HEAR
20 ME?

21 CHAIRMAN KLEIN: I CAN. THANK YOU.

22 MS. SAMUELSON: I HAVE A LOT OF THOUGHTS
23 ABOUT THIS. I'LL JUST PICK ONE. I GUESS -- IT'S
24 HARD TO DO THIS WITH THAT FEEDBACK, SO I'LL BE
25 BRIEF. I THINK IT'S IMPORTANT THAT WE BE AS

BARRISTERS' REPORTING SERVICE

1 FLEXIBLE AS POSSIBLE AND AS INNOVATIVE IN THE
2 MECHANISM -- RESEARCH FUNDING MECHANISMS WE CHOOSE.
3 IT WOULD BE GREAT TO JUST FUND ONE IF THAT WAS THE
4 ONE THAT'S GOING TO PUSH THE SCIENCE AHEAD AND PUSH
5 A THERAPY. I'LL QUIT AT THAT. THIS IS HARD TO DO.

6 CHAIRMAN KLEIN: ALL RIGHT. I'D ALSO LIKE
7 TO ASK THAT WE'VE HAD A NUMBER OF ROUNDS EARLY ON TO
8 CREATE AN INFRASTRUCTURE AND A PIPELINE OF EMBRYONIC
9 STEM CELL RESEARCH. WE HAVE A NUMBER OF GRANTS THAT
10 WERE DEDICATED TO EMBRYONIC STEM CELL RESEARCH.
11 THEY MAY HAVE HAD PARALLEL STUDIES, PLURIPOTENT --
12 CORD BLOOD STEM CELLS AND EMBRYONIC COMPARING THEM.
13 AND THESE VARIOUS OUTCOMES FROM THOSE EMBRYONIC STEM
14 CELL STUDIES MAY LEAD TO A THERAPY THAT IS NOT A
15 CELLULAR THERAPY, BUT WAS DERIVED FROM AN EMBRYONIC
16 STEM CELL GRANT. THERE'S A VALUE IN THAT.

17 I WOULD GUESS THERE'S ALSO A SMALL AMOUNT
18 OF THOSE THAT ARE AT AN IND LEVEL AS WELL. BUT IN
19 ORDER TO BROADLY VALIDATE THE SPECTRUM OF HOW
20 EMBRYONIC STEM CELL RESEARCH CAN CONTRIBUTE, CAN WE
21 ALSO INCORPORATE IN THIS SPECIFICALLY AND NARROWLY
22 THERAPIES THAT WERE DERIVED FROM CIRM EMBRYONIC STEM
23 CELL GRANTS THAT MAY BE QUALIFIED FOR AN IND EVEN IF
24 THEY MAY NOT BE A CELLULAR THERAPY?

25 DR. TROUNSON: WELL, I'D ARGUE AGAINST

BARRISTERS' REPORTING SERVICE

1 THAT BECAUSE I THINK YOU'D BRING A VERY LARGE NUMBER
2 OF GRANTS FORWARD OR POTENTIALLY. AND I THINK WE
3 WANT TO BE -- I THINK WE HEARD FROM THE BOARD AT THE
4 LAST MEETING OR THE MEETING BEFORE ABOUT HOW
5 IMPORTANT IT IS TO GET SOME OF THESE PLURIPOTENTIAL
6 STEM CELL THERAPIES THERE. AND I THINK IF WE COLOR
7 IT BY DOING THAT, CHAIR, I THINK WE WILL PROBABLY
8 NOT BE SUCCESSFUL IN MY OWN VIEW.

9 IT SAYS VERY SPECIFICALLY IN THE MISSION,
10 THAT I CONTINUOUSLY NEED TO READ, THIS IS A
11 PLURIPOTENTIAL STEM CELL THERAPY THAT NEEDS TO GET
12 THERE. THE OTHERS, I THINK THEY'RE COMING ALONG
13 BEAUTIFULLY, AND WE SAW THEM IN THE DISEASE TEAMS.
14 I THINK THEY'RE GOING TO GET SWEEPED UP IN THE NEW
15 DISEASE TEAMS COMING THROUGH.

16 BUT I WOULD LIKE TO PICK UP THE
17 PLURIPOTENTIAL STEM CELL THERAPEUTICS THAT ARE
18 THERE. THERE IS AT LEAST THREE OF THEM, I THINK,
19 WHO ARE STRUGGLING AT THE MOMENT OUT AT THAT FRONT
20 LEVEL. AND IF IT'S POSSIBLE THAT THEY MEET THE
21 CRITERIA THAT WE DEMAND OF THEM, THEN I THINK WE
22 NEED TO GET IN BESIDE THEM AND GO THROUGH THIS SPACE
23 TOGETHER.

24 CHAIRMAN KLEIN: I HOPE AS WE PUT THIS OUT
25 WE FIND THERE'S SIGNIFICANTLY GREATER, BUT I

BARRISTERS' REPORTING SERVICE

1 UNDERSTAND YOUR COMMENTS. DR. FRIEDMAN.

2 DR. FRIEDMAN: JUST VERY QUICKLY. I THANK
3 YOU AND MY FELLOW BOARD MEMBERS. A NUMBER OF THE
4 CONCERNS I HAVE I FEEL ARE BEING ADDRESSED, AND SOME
5 OF MY CONCERNS AND RESERVATIONS, I THINK, HAVE BEEN
6 DEALT WITH.

7 I WOULD LIKE TO TAKE JUST ONE BRIEF
8 SECOND, THOUGH, AND REINFORCE WHAT DR. HAWGOOD SAID
9 EARLIER. I'D LIKE NOT TO HAVE THE DISCUSSION TODAY;
10 BUT WHEN YOU COME BACK WITH THE RFA, I THINK THE
11 QUESTION OF DO WE FOLLOW PATIENTS WHO RECEIVE
12 EMBRYONIC STEM CELL THERAPIES FOR VERY LONG PERIODS
13 OF TIME, EVEN THEIR LIFETIME, I THINK IS A REALLY
14 VALID SCIENTIFIC QUESTION. AND YOUR POINT, IF I
15 UNDERSTOOD IT, WAS SHOULD WE BUILD INTO THAT SOME
16 FINANCES FOR THE LONG TERM. THESE CAN BE PERIODIC,
17 THEY CAN BE BANKING, IT DOESN'T HAVE TO BE A LOT OF
18 MONEY, BUT I FEAR IF WE DON'T BUILD IT IN NOW, IN
19 FACT, WE WON'T DO IT. AND WE HAVE A REALLY
20 SUBSTANTIAL OBLIGATION, NOT FROM FDA NECESSARILY,
21 BUT I THINK TO THE SCIENTIFIC COMMUNITY, AND I ASK
22 YOU PLEASE TO THINK ABOUT THAT AS WE GO FORWARD.

23 DR. TROUNSON: THANK YOU. WE'LL TAKE THAT
24 ON BOARD, MICHAEL. WE'LL TAKE IT IN-HOUSE AND WE'LL
25 HOPEFULLY HAVE A RESPONSE FOR YOU.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SO LET ME ASK THE MAKER
2 OF THE MOTION TO CLARIFY. WE HAVE DISCUSSED A
3 NUMBER OF TECHNICAL POINTS FROM VARIOUS BOARD
4 MEMBERS TO WHERE THE PRESIDENT WILL NEED DISCRETION
5 TO MODIFY THE TECHNICAL ELEMENTS OF THIS TO BE ABLE
6 TO ADAPT TO THE FACTS OF THE APPLICATIONS TO MAKE
7 SURE SUBSTANTIVELY WE CAPTURE OUR GOAL WITHOUT
8 TECHNICALLY DEFEATING A GOOD APPLICATION.

9 IS IT THE INTENT OF YOUR MOTION TO PROVIDE
10 THE PRESIDENT WITH THAT KIND OF DISCRETION, TO
11 MODIFY THESE VERY SPECIFIC GUIDELINES SO THAT, FOR
12 EXAMPLE, HE COULD HAVE THE PI HAVING 20 PERCENT AND
13 THE CO-PI HAVING 30 PERCENT, BUT ESSENTIALLY
14 ACCOMPLISHING THE INTENT OF THE GUIDELINES WITHOUT
15 TECHNICALLY BEING EXACTLY ALIGNED WITH THIS DETAIL?

16 DR. PRIETO: SURE. THIS IS A CONCEPT
17 PROPOSAL, AND I THINK THE DETAILS WILL COME OUT WHEN
18 THE ACTUAL RFA COMES TO US. AND I BASICALLY FEEL
19 STRONGLY THE WAY JEFF DOES. I THINK THIS IS WHERE
20 WE SHOULD BE MOVING.

21 CHAIRMAN KLEIN: DR. LOVE, IS THAT
22 ACCEPTABLE TO YOU AS THE SECOND?

23 DR. LOVE: I GUESS IT IS. I'M NOT
24 ENTIRELY SURE, THOUGH, WHERE WE'RE GIVING LEEWAY,
25 AND I'M NOT ENTIRELY SURE WHERE LEEWAY IS REQUESTED.

BARRISTERS' REPORTING SERVICE

1 DR. OLSON: I WOULD NOTE THAT IN THE RFA
2 WE TYPICALLY ALLOW TO PETITION THE PRESIDENT FOR
3 PERCENT EFFORT CHANGES, SO THAT IS TYPICALLY
4 INCORPORATED IN EVERY RFA AT THE DISCRETION OF THE
5 PRESIDENT. SO I'M NOT SURE IT REQUIRES A MOTION BY
6 THE BOARD OR INCLUSION IN THE MOTION.

7 CHAIRMAN KLEIN: SO, FOR EXAMPLE, DR.
8 OLSON, IN YOUR COMMENTS YOU SUGGESTED THAT THE TERM
9 COULD BE EXTENDED BY THE PRESIDENT, BUT THAT'S NOT
10 IN THE SUMMARY WE HAVE BEFORE US.

11 DR. OLSON: THAT TYPICALLY IS IN THE RFA.
12 OBVIOUSLY THERE ARE MANY DETAILS IN THE RFA THAT
13 THIS BOARD DOES NOT DEAL WITH. WE COME TO YOU WITH
14 WHAT WE THINK ARE SOME OF THE KEY ASPECTS OF IT, THE
15 SCOPE, THE DOLLARS, YOU KNOW. SO THAT'S WHAT WE DO.

16 MS. SAMUELSON: ARE WE GOING TO BE ABLE TO
17 SEE THE FINAL DRAFT OF THE RFA?

18 CHAIRMAN KLEIN: JOAN, WHAT IS YOUR
19 COMMENT?

20 MS. SAMUELSON: I'M WONDERING IF WE'RE
21 GOING TO BE ABLE TO SEE AND SIGN OFF ON A DRAFT WITH
22 MORE SPECIFICS.

23 CHAIRMAN KLEIN: I'M GOING TO ASK ONE OF
24 THE STAFF MEMBERS, JOAN, TO CALL YOU SO WE CAN GET A
25 CLEAR STATEMENT OF YOUR QUESTION.

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: SURE.

2 MR. HARRISON: I BELIEVE SHE REQUESTED
3 WHETHER THE BOARD WILL HAVE THE OPPORTUNITY TO SIGN
4 OFF ON THE RFA. AND THE ANSWER IS THAT THE BOARD
5 ONLY APPROVES THE CONCEPT. THE DETAILS ARE IN
6 STAFF'S HANDS IN THE DRAFTING OF THE FINAL RFA.

7 MS. SAMUELSON: I GUESS I'M HEARING AN
8 INTEREST BY SEVERAL OF THE BOARD MEMBERS TO HAVE
9 INPUT AT AN LATER STAGE.

10 CHAIRMAN KLEIN: DAVID SERRANO-SEWELL, DO
11 YOU HAVE A COMMENT?

12 MR. SERRANO-SEWELL: HISTORICALLY, AS
13 JAMES HARRISON HAS SAID, WE GIVE CONCEPT APPROVAL TO
14 STAFF. I WASN'T SURE IF THAT PRECLUDED US FROM
15 GIVING FURTHER DIRECTION AND COMMENTS TO STAFF ON
16 THE RFA -- RFP. PERHAPS IT DOES. I DON'T THINK IT
17 DOES LEGALLY.

18 CHAIRMAN KLEIN: SO OUR PROCESS HAS BEEN
19 TO GIVE CONCEPT APPROVAL. IF A BOARD MEMBER
20 DISCOVERS INFORMATION THEY THINK MIGHT BE HELPFUL TO
21 STAFF, IT CAN BE COMMUNICATED TO STAFF, BUT THE
22 DISCRETION IS AT THE STAFF LEVEL.

23 MR. ROTH: IS THERE A MOTION AND A SECOND?

24 CHAIRMAN KLEIN: DID YOU ACCEPT THE
25 MODIFICATION?

BARRISTERS' REPORTING SERVICE

1 DR. LOVE: YES.

2 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

3 MR. ROTH: I'LL CALL THE QUESTION.

4 CHAIRMAN KLEIN: ALL RIGHT. IF I COULD
5 HAVE A ROLL CALL, PLEASE.

6 DR. FRIEDMAN REMINDS ME THAT I HAVE NOT
7 CALLED FOR THE PUBLIC COMMENT, WHICH I'D LIKE TO DO
8 AT THIS TIME.

9 MR. REED: THIS IS ONE OF THE MOST
10 EXCITING DEVELOPMENTS THAT HAS COME ABOUT. I TALKED
11 WITH A PARALYZED PERSON IN A VERY TERRIBLE STRAIT
12 RECENTLY. SHE SAID SHE HAD DECIDED THAT IF THERE
13 WAS NO PROGRESS TOWARD HOPE WITHIN A YEAR THAT SHE
14 WAS GOING TO COMMIT SUICIDE. THIS IS A TREMENDOUS
15 STEP FORWARD. MY GUT INSTINCT IS THAT THIS WILL
16 ADVANCE THE ENTIRE FIELD. CONGRATULATIONS. I HOPE
17 THAT YOU WILL AGREE, AND I THINK THAT YOU WILL.
18 THANK YOU.

19 MS. ROBERSON: HELLO. JUDY ROBERSON WITH
20 HUNTINGTON'S DISEASE. SO I DID HAVE A QUESTION.
21 WHY WAS THIS RFA LIMITED ONLY TO PLURIPOTENT STEM
22 CELLS? OUR CONCERN IS THAT WE HAVE VERY -- THERE'S
23 VERY LIMITED FUNDING FOR ANY CLINICAL TRIALS. SO
24 THAT'S MY QUESTION.

25 CHAIRMAN KLEIN: THANK YOU. AND, DR.

BARRISTERS' REPORTING SERVICE

1 OLSON, COULD YOU PLEASE RESPOND? JUDY, I'D REMIND
2 YOU THAT DISEASE TEAM II WILL BE MUCH BROADER AND
3 WOULD HAVE THE FULL SPECTRUM OF CELLULAR THERAPIES.
4 DR. OLSON HAS TOLD US THAT THAT WILL INCLUDE A
5 PROVISION FOR CLINICAL TRIALS.

6 DR. OLSON: THAT IS CORRECT. SO BOB HAS
7 RESPONDED TO THE QUESTION. MR. CHAIRMAN HAS
8 RESPONDED. THANK YOU.

9 CHAIRMAN KLEIN: MR. HARRISON.

10 MR. HARRISON: I WAS JUST GOING TO MAKE A
11 SUGGESTION. WE DO NOT NEED A ROLL CALL VOTE EXCEPT
12 FOR THOSE MEMBERS WHO ARE ON THE PHONE. SO UNLESS
13 YOU WOULD LIKE TO HAVE ONE, WE CAN JUST --

14 CHAIRMAN KLEIN: SO WE WILL CALL THE
15 QUESTION FOR THE MEMBERS PRESENT, AND THEN WE'LL
16 TAKE A ROLL CALL OF THE MEMBERS ON THE PHONE.

17 ALL IN FAVOR.

18 (CHORUS OF AYES.)

19 CHAIRMAN KLEIN: OPPOSED? LET IT BE KNOWN
20 THAT THERE ARE NONE PRESENT WHO ARE OPPOSED. AND
21 PLEASE CALL THE ROLL OF THOSE ON THE PHONE.

22 MS. KING: JOAN SAMUELSON. JON SHESTACK,
23 ARE YOU ON THE LINE?

24 MR. SHESTACK: YES, I AM.

25 MS. KING: AND WHAT IS YOUR VOTE, PLEASE?

BARRISTERS' REPORTING SERVICE

1 MR. SHESTACK: AYE.

2 MS. KING: JOAN SAMUELSON, ARE YOU STILL
3 ON THE PHONE?

4 CHAIRMAN KLEIN: SO IF YOU WOULD CALL HER
5 PERSONALLY, I'D LIKE TO RECORD WHAT HER VOTE IS.
6 I'M GOING TO KEEP THE ROLL OPEN UNTIL HER VOTE IS
7 RECORDED. MAKE SURE THAT SHE CAN BE ON THE RECORD
8 ACCORDING TO HER WISHES.

9 I'D LIKE TO THANK THE STAFF FOR THEIR
10 TREMENDOUS LEADERSHIP AND EFFORT ON THIS, DR. OLSON
11 AND AN HER TEAM, DR. TROUNSON, THE COUNSEL, ALL OF
12 THE MEMBERS OF THE PRESIDENT'S TEAM.

13 ALL RIGHT. WITH THAT, I'D LIKE TO GO TO
14 THE LEGISLATIVE REPORT. ACTUALLY, IF WE CAN, MAYBE
15 WE COULD TRY AND QUICKLY ADDRESS ITEM -- THE
16 PRECEDING ITEM FIRST. NOW THAT WE HAVE EVERYONE
17 BACK IN THE ROOM FROM LEGISLATIVE VISITS, ASK IS
18 THERE A MOTION TO APPROVE THE MINUTES?

19 MS. LANSING: SO MOVED.

20 CHAIRMAN KLEIN: SO MOVED BY SHERRY
21 LANSING. IS THERE A SECOND? SECOND BY LEEZA
22 GIBBONS.

23 ALL IN FAVOR.

24 (CHORUS OF AYES.)

25 CHAIRMAN KLEIN: OPPOSED?

BARRISTERS' REPORTING SERVICE

1 (NO RESPONSE.)

2 CHAIRMAN KLEIN: OKAY. ANY PUBLIC
3 COMMENTS ON THE MINUTES? I WILL REOPEN THE VOTE IF
4 THERE ARE. I DON'T SEE ANY. THANK YOU. COULD YOU
5 CALL THE ROLL ON THE ONES ON THE PHONES.

6 MS. KING: RELATED TO THE MINUTES, MR.
7 SHESTACK, PLEASE. DO WE STILL HAVE JON SHESTACK
8 WITH US ON THE PHONE?

9 MR. SHESTACK: YES. AYE.

10 MS. KING: THERE'S A MOTION ON THE TABLE
11 TO APPROVE THE MINUTES. YOU SAID AYE.

12 MR. SHESTACK: YES, I APPROVE. I APPROVED
13 THEM. SORRY I DIDN'T SPEAK LOUD ENOUGH.

14 MS. KING: JOAN SAMUELSON, ARE YOU ON THE
15 LINE? WE WOULD JUST LIKE YOUR VOTE IF WE COULD,
16 PLEASE.

17 MS. SAMUELSON: THIS IS JOAN.

18 CHAIRMAN KLEIN: JOAN, GO AHEAD.

19 MS. SAMUELSON: SORRY. I WAS OFF THE LINE
20 WITH JENNA. IS THERE A QUESTION FOR ME?

21 MS. KING: YES. WHAT WE'D LIKE TO KNOW IS
22 WHAT YOUR VOTE IS WITH RESPECT TO THE MOTION ON THE
23 TABLE TO APPROVE THE MINUTES. THERE ARE FOUR SETS
24 OF MINUTES.

25 MS. SAMUELSON: AYE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

2 MS. KING: THANK YOU. ACTUALLY JUST TO
3 HAVE IT ON THE RECORD, EVEN THOUGH YOU TOLD ME OVER
4 THE PHONE, COULD YOU PLEASE LET EVERYBODY KNOW WHAT
5 YOUR VOTE WAS WITH RESPECT TO THE CONCEPT APPROVAL
6 FOR CLINICAL TRIALS?

7 MS. SAMUELSON: AYE.

8 MS. KING: THANK YOU.

9 MS. LANSING: I THINK WE'VE ALL READ THE
10 BIOS ON THE GRANTS WORKING GROUP, AND I'D LIKE TO
11 MOVE APPROVAL AND THEN OPEN IT FOR DISCUSSION.

12 DR. PULIAFITO: SECOND.

13 CHAIRMAN KLEIN: THERE'S A MOTION BY
14 SHERRY LANSING, A SECOND BY DR. PULIAFITO. COMMENT
15 FROM THE BOARD? COMMENT FROM THE PUBLIC ON THE
16 WORKING GROUP MEMBERS? I'D LIKE TO CALL THE
17 QUESTION. ALL IN FAVOR.

18 (CHORUS OF AYES.)

19 CHAIRMAN KLEIN: OPPOSED.

20 (NO RESPONSE.)

21 CHAIRMAN KLEIN: CALL THE ROLL, PLEASE, OF
22 THOSE ON THE PHONE.

23 MS. KING: JOAN SAMUELSON, YOUR VOTE
24 PLEASE.

25 MS. SAMUELSON: AYE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: AND JONATHAN SHESTACK, YOUR
2 VOTE PLEASE.

3 CHAIRMAN KLEIN: I'M GOING TO LEAVE THE
4 ROLL OPEN UNTIL WE HEAR FROM JONATHAN SHESTACK.
5 SOME INDICATIONS ARE THAT HE CAN HEAR US, BUT WE
6 CAN'T ALWAYS HEAR HIM.

7 MR. SHESTACK: HELLO.

8 MS. KING: YOUR VOTE WAS AYE; IS THAT
9 CORRECT, MR. SHESTACK?

10 MR. SHESTACK: YES, IT WAS. YES. I'M
11 SORRY.

12 MS. LANSING: (OFF MIC) I JUST WANT TO
13 (INAUDIBLE).

14 CHAIRMAN KLEIN: SHERRY MAKING THAT
15 MOTION. DUANE ROTH IS THE SECOND. AND AS A
16 FRIENDLY AMENDMENT, THERE ARE MEMBERS OF THE BOARD,
17 JEFF SHEEHY, DUANE ROTH, YOURSELF WHO WORKED WITH
18 STUART. I WOULD THINK THAT PERHAPS THAT WE COULD
19 GET TOGETHER AFTER THE MEETING AND ADD SOME REAL
20 STRENGTH TO THIS RESOLUTION. THE INTENT IS THERE,
21 BUT WE HAVE SOME REALLY STRONG STATEMENTS WE CAN
22 MAKE ABOUT HIS LEADERSHIP.

23 MS. LANSING: I ACCEPT THE FRIENDLY
24 AMENDMENT. AND HAVING WORKED WITH HIM, ANYTHING
25 THAT YOU CAN POSSIBLY DO TO MAKE IT STRONGER AND

BARRISTERS' REPORTING SERVICE

1 MORE POSITIVE AND MORE FILLED WITH GRATITUDE, I
2 WOULD SUPPORT.

3 MR. ROTH: IT'S ACCEPTED.

4 CHAIRMAN KLEIN: IT'S ACCEPTED BY THE
5 MAKER AND THE SECOND. MY UNDERSTANDING IS NO PUBLIC
6 COMMENT, INCLUDING MY MOTION -- MY REQUEST FOR
7 AMENDMENT. I'M GOING TO CALL FOR THE QUESTION. ALL
8 IN FAVOR.

9 (CHORUS OF AYES.)

10 CHAIRMAN KLEIN: OPPOSED?

11 (NO RESPONSE.)

12 CHAIRMAN KLEIN: AND ON THE PHONE.

13 MR. SHESTACK: AYE.

14 MS. KING: JON SHESTACK'S VOTE IS AYE.

15 MS. SAMUELSON: AYE.

16 MS. KING: AND JOAN SAMUELSON'S VOTE IS
17 AYE.

18 CHAIRMAN KLEIN: WE HAVE A VERY IMPORTANT
19 ITEM HERE, ITEM 7, THEN WE'RE GOING TO THE
20 LEGISLATIVE ITEM. CAN DR. TROUNSON INDICATE WHO
21 WILL MAKE THE PRESENTATION?

22 LET ME ASK THE BOARD FOR A MINUTE. DOES
23 THE BOARD WANT TO TAKE A THREE- OR FOUR-MINUTE
24 RECESS? KEEP GOING. ALL RIGHT.

25 DR. TROUNSON: DR. PATRICIA OLSON WILL

BARRISTERS' REPORTING SERVICE

1 PRESENT THIS ON BEHALF OF STAFF.

2 DR. OLSON: MR. CHAIRMAN, MEMBERS OF THE
3 BOARD, AND MEMBERS OF THE AUDIENCE, I STAND BEFORE
4 YOU AGAIN. SO WHAT I WANT TO TALK ABOUT NOW IS
5 AGENDA ITEM NO. 7 IN YOUR BINDER. AND I WANTED TO
6 REMIND YOU WHAT THIS ITEM IS ABOUT. IT'S A PROPOSED
7 ACTION TO APPROVE ADDITIONAL -- A FUNDING INCREASE
8 FOR THE EARLY TRANSLATIONAL RESEARCH AWARD TR1-01267
9 ENTITLED "DEVELOPMENT CANDIDATES FOR CELL-BASED
10 THERAPIES FOR PARKINSON'S DISEASE."

11 AND WHAT I WANT TO DO IS GIVE YOU A LITTLE
12 BIT OF BACKGROUND TO THIS BEFORE I MOVE ON. FIRST,
13 THIS APPLICATION WAS SUBMITTED IN RESPONSE TO OUR
14 FIRST EARLY TRANSLATIONAL RFA, WHICH WAS ESSENTIALLY
15 AN IMPORTANT PART OF OUR PIPELINE DEVELOPMENT TO
16 IDENTIFY DEVELOPMENT CANDIDATES AND BOTTLENECKS TO
17 CELL THERAPIES. SO THAT WAS THE SCOPE OF THIS RFA.

18 THIS PARTICULAR APPLICATION RECEIVED A
19 STRONG AND ENTHUSIASTIC RECOMMENDATION FROM THE
20 GRANTS WORKING GROUP. AND IN RESPONSE TO THAT
21 RECOMMENDATION AND YOUR ASSESSMENT OF THE VALUE OF
22 THE RESEARCH AND ITS POTENTIAL AND THE POTENTIAL OF
23 ITS BENEFIT FOR PATIENTS WITH PARKINSON'S DISEASE,
24 YOU APPROVED THE AWARD FOR FUNDING.

25 THE GOAL OF THIS AWARD IS, IN FACT, TO

BARRISTERS' REPORTING SERVICE

1 SELECT AND DEVELOP THE BEST CANDIDATE CELL FOR
2 POTENTIAL THERAPY OF PARKINSON'S DISEASE. SO LET ME
3 PROVIDE A BIT MORE DETAIL HERE.

4 WHAT THE AWARD PROPOSES IS TO ESSENTIALLY
5 TAKE FULLY CHARACTERIZED AND TO TEST IN VIVO AND IN
6 VITRO NEURAL STEM CELLS DERIVED FROM SIX DIFFERENT
7 SOURCES. YOU MAY ALL REMEMBER, AND I BELIEVE IT
8 WAS, I MAY GET MY DATES WRONG, BUT IN THE LATE '80S
9 AND '90S, THERE WERE TRIALS CONDUCTED OF CELL
10 THERAPIES WHERE CELLS WERE IMPLANTED INTO THE BRAINS
11 OF PATIENTS WITH PARKINSON'S DISEASE. AND AT LEAST
12 INITIAL CLINICAL RESULTS WERE VERY DRAMATIC IN SOME
13 SMALL NUMBER OF PATIENTS; BUT WHEN SUBSEQUENT
14 CONTROLLED TRIALS WERE DONE, IT DIDN'T MEET THE
15 PRIMARY END POINT, ALTHOUGH, AGAIN, THERE WERE SOME
16 EXAMPLES OF PATIENTS THAT WERE SUCCESSFULLY TREATED
17 AND ESSENTIALLY RESPONDED TO THE THERAPY.

18 THERE WAS SOME THOUGHT THAT AT THAT TIME
19 THAT THE CELL POPULATIONS THAT WERE USED WERE NOT
20 RIGOROUSLY -- WHAT DO I WANT TO SAY? -- CONSISTENT
21 AND CHARACTERIZED. EVEN NOW THERE'S TALK AT THE NIH
22 OF POSSIBLY FUNDING ANOTHER TRIAL WITH, SAY,
23 FETAL-DERIVED CELLS. SO IN SOME SENSES I WOULDN'T
24 GO SO FAR AS TO SAY THERE'S CLINICAL PROOF OF
25 CONCEPT, BUT THERE'S TANTALIZING EVIDENCE THAT, IN

BARRISTERS' REPORTING SERVICE

1 FACT, CELL REPLACEMENT FOR PARKINSON'S DISEASE IS
2 SOMETHING WORTH CONSIDERING AND WORTH PURSUING.

3 SO WHAT THIS APPLICATION SPECIFICALLY
4 PROPOSES TO DO IS TO GET NEURAL STEM CELLS FROM SIX
5 DIFFERENT SOURCES AND TO VERY FULLY CHARACTERIZE
6 THEM AND TEST THEM IN VIVO AND IN VITRO. AND THE IN
7 VIVO TESTING WOULD TAKE PLACE IN WHAT IS, I THINK,
8 REGARDED IN THE RESEARCH COMMUNITY AS THE BEST MODEL
9 OF PARKINSON'S DISEASE, THE MOST ANALOGOUS TO THE
10 HUMAN DISEASE THAT ACTUALLY EXISTS.

11 SO THAT'S WHAT THIS PROPOSAL WAS TO DO,
12 AND THE MODEL BEST RECAPITULATES THE HUMAN COURSE OF
13 DISEASE AND IS GENERALLY RECOGNIZED AS BEING TRUE.

14 THE STUDIES ON THIS MODEL WERE ALL
15 BUDGETED IN A SUBCONTRACT FOR SUPPLIES, SERVICES,
16 AND RESEARCH OUTSIDE OF CALIFORNIA. SO THAT
17 SUBCONTRACT FOR THE STUDIES IN THIS MODEL, IT'S AN
18 EXTERNAL TO CALIFORNIA CONTRACT, IT INCLUDED
19 SUPPLIES, SERVICES, AND RESEARCH ACTIVITIES. THE
20 SUBCONTRACT WAS JUSTIFIED IN THE BUDGET SECTION OF
21 THE APPLICATION. THE REVIEWERS WERE AWARE OF IT.
22 THEY DID READ IT.

23 AS IS CIRM'S POLICY AND OUR STANDARD
24 PRACTICE, DURING PREFUNDING ADMINISTRATIVE REVIEW,
25 THAT IS, BEFORE WE ISSUE A NOTICE OF AWARD, CIRM

BARRISTERS' REPORTING SERVICE

1 REVIEWS THE PROPOSAL, INCLUDING THE BUDGET, FOR
2 ALLOWABLE EXPENSES. WE REVIEWED THE PROPOSED
3 SUBCONTRACT. AS YOU KNOW, CIRM HAS A POLICY AND THE
4 BOARD AND, I BELIEVE, THE PROPOSITION 71 HAS A
5 POLICY THAT HAS A PREFERENCE FOR PURVEYORS IN
6 CALIFORNIA OF SUPPLIES AND SERVICES. IT IS A
7 PREFERENCE. AND GENERALLY WE TRY AND DO THAT ALL
8 ALONG.

9 CIRM DETERMINED, GIVEN THE ABSOLUTE UNIQUE
10 NATURE OF THE SUPPLIES AND SERVICES PROVIDED IN THIS
11 SUBCONTRACT AND THEIR INABILITY TO BE DUPLICATED
12 ELSEWHERE, THAT IT WOULD ALLOW THE COSTS ASSOCIATED
13 WITH SUPPLIES AND SERVICES, BUT WOULD NOT ALLOW THE
14 COST ASSOCIATED WITH THE EXTRA OUTSIDE OF CALIFORNIA
15 RESEARCH ACTIVITIES.

16 SO --

17 CHAIRMAN KLEIN: SO, DR. OLSON, BECAUSE
18 WORDS ARE VERY IMPORTANT HERE, LET ME EMPHASIZE A
19 COUPLE OF THEMES WITH SOME CLEAN LINES HERE. MY
20 UNDERSTANDING IS ALL THE RESEARCH WILL BE IN
21 CALIFORNIA. THE DISEASE MODEL IS WHAT WE'RE TALKING
22 ABOUT, ANIMAL DISEASE MODEL AS BEING A UNIQUE
23 RESOURCE WOULD BE OUTSIDE OF CALIFORNIA. IT JUST
24 CAN'T BE REPLICATED IN CALIFORNIA TO GET THE KIND OF
25 BEST POTENTIAL RESULTS.

BARRISTERS' REPORTING SERVICE

1 SO THIS IS A SITUATION WHERE, AS YOU SAY,
2 WE HAVE A PREFERENCE FOR VENDORS IN THE STATE. BUT
3 THE RESEARCH ON THIS IS WITHIN CALIFORNIA. THAT'S
4 THE RESEARCH WE'RE FUNDING, WHICH IS A VERY
5 IMPORTANT DISTINCTION IN WHAT WE FUND OUT OF THE
6 BOND FUNDS THAT ARE RAISED IN CALIFORNIA. BUT WHEN
7 WE NEED TO GET AN ANIMAL MODEL OR SPECIAL EQUIPMENT
8 OR SPECIAL SERVICES THAT ARE CRITICAL TO RESEARCH,
9 WE CAN SOURCE THAT OUT OF STATE.

10 IS THAT A CORRECT CHARACTERIZATION, MR.
11 HARRISON?

12 MR. HARRISON: YES.

13 DR. OLSON: SO FOR THAT PART OF THE
14 CONTRACT THAT INCLUDED RESEARCH, CIRM WENT TO ASK
15 THE PI TO PROPOSE ALTERNATIVES THAT WOULD ALLOW
16 ESSENTIALLY THE RESEARCH TO BE CONDUCTED WITHIN
17 CALIFORNIA IN ACCORDANCE WITH THE GOALS OF THE
18 PROPOSAL.

19 AND SO WHAT THE PI DID WAS MADE A PROPOSAL
20 TO MOVE THOSE RESEARCH ACTIVITIES THAT WERE PART OF
21 THE SUBCONTRACT IN-HOUSE. SO SOME OF THE
22 CHARACTERIZATION STUDIES WERE TO BE MOVED IN-HOUSE
23 TO THE GRANTEE INSTITUTION. AND THE IMPACT ON
24 THE -- THERE WAS A DRAFT BUDGET SUBMITTED FOR THE
25 COST OF MOVING THOSE RESOURCES IN-HOUSE, AND THE

BARRISTERS' REPORTING SERVICE

1 IMPACT IS OBVIOUSLY ONE OF COST.

2 CHAIRMAN KLEIN: DR. OLSON, COULD YOU
3 COMMENT? IS THIS AN AWARD WITH A BILATERAL FUNDING
4 PARTNER?

5 DR. OLSON: THIS IS AN AWARD THAT DOES
6 INCLUDE AN AUSTRALIAN FUNDING PARTNER, BUT THE
7 RESEARCH THAT WAS TO BE CONDUCTED BY THE AUSTRALIAN
8 FUNDING PARTNER IS NOT AFFECTED BY THIS. THAT
9 RESEARCH STILL WILL GO FORWARD. I WOULD POINT OUT
10 THE AUSTRALIAN FUNDING PARTNER HAS BEEN ON HOLD
11 WHILE WE WORK THROUGH THE ISSUES ASSOCIATED WITH IT.

12 CHAIRMAN KLEIN: RIGHT. SO FOR
13 CLARIFICATION, CALIFORNIA FUNDS DO NOT FUND ANY PART
14 OF THE AUSTRALIAN FUNDING PARTNER. THAT IS ALL
15 FUNDED BY AUSTRALIA.

16 DR. OLSON: FUNDED BY OUR COLLABORATIVE
17 FUNDING PARTNER. YOU MAY RECALL THIS WAS ACTUALLY
18 THE FIRST RFA WHERE WE HAD -- THE COLLABORATIVE
19 FUNDING PARTNER PROGRAM WAS PUT INTO EFFECT. AND
20 ACTUALLY THIS AWARD WAS SUCCESSFUL AND INCLUDED A
21 COLLABORATIVE FUNDING PARTNER. SO THAT IS A CORRECT
22 STATEMENT.

23 SO WHAT WE DID IN THE ASSESSMENT OF THE
24 PROPOSED CHANGES TO ESSENTIALLY CONDUCT THE
25 ACTIVITIES THAT WERE TO HAVE BEEN -- TO CONDUCT ALL

BARRISTERS' REPORTING SERVICE

1 THE RESEARCH ACTIVITIES IN CALIFORNIA, AS WE
2 CONDUCTED AN INTERNAL ASSESSMENT. WE RETAINED AN
3 EXTERNAL CONSULTANT TO LOOK OVER THE PROPOSED
4 CHANGES, AND WE CONDUCTED A SITE VISIT AT THE
5 INSTITUTION.

6 AND AS A RESULT OF ALL THOSE ACTIVITIES,
7 WE BECAME CONVINCED THAT AT LEAST THE RESEARCH COULD
8 MOVE AHEAD AS PROPOSED ALTHOUGH IT WOULD BE AT AN
9 ADDED COST. I'D LIKE TO GO INTO THOSE CHANGES HERE.

10 SO IF YOU LOOK AT THIS SLIDE, BASICALLY
11 THERE ARE DIRECT PROJECT COSTS AND IN THE -- SO
12 THEY'RE INCREASED ROUGHLY, WHAT, 900,000, I GUESS,
13 IN YEAR ONE FOR THE -- NOT IN YEAR ONE, ACROSS THE
14 BUDGET FOR THE DIRECT COSTS. THIS IS MAINLY DUE TO
15 AN INCREASE IN FTE'S AND THE ASSOCIATED COST OF
16 THOSE FTE'S IN CALIFORNIA. AND LET ME EXPLAIN WHY
17 THAT IS.

18 THE PERSONNEL WHO WERE GOING TO CONDUCT
19 THIS RESEARCH EXTERNAL TO CALIFORNIA AS PART OF THIS
20 SUBCONTRACT ARE PERSONS WHO HAVE BEEN DOING THESE
21 KINDS OF STUDIES FOR OVER 20 YEARS. YOU ASK TO
22 TRANSFER THAT KIND OF EXPERTISE AND EXPERIENCE TO
23 ESSENTIALLY PEOPLE WHO ARE NOT TOTALLY FAMILIAR WITH
24 THAT, AND IT BASICALLY TAKES SOME TIME AND MONEY.
25 SO WHAT WE'RE DOING IS WE'RE REPLACING ROUGHLY

BARRISTERS' REPORTING SERVICE

1 \$400,000 IN 20 YEARS OF EXPERIENCE WITH RESEARCH
2 COSTS WITH THESE INTERNAL PEOPLE.

3 NOW, WE WILL BE HAVING -- THE HEAD OF THE
4 GROUP WHO CONDUCTED THIS BEFORE WILL BE VISITING THE
5 SITE PERIODICALLY TO ASSESS. THE CONSULTANT ALSO
6 SUGGESTED INCLUDING MILESTONES ON THE PERFORMANCE OF
7 THESE COMPLEX ASSAYS, AND THAT WE WILL DO. SO WE
8 WILL MEASURE AND MAKE SURE THAT THE PROPOSED STAFF
9 IS ABLE TO TAKE ON THESE.

10 I DON'T WANT YOU TO THINK THAT THESE
11 PEOPLE AREN'T VERY GOOD. I MEAN THESE ARE PEOPLE --
12 THESE ARE GENERALLY POST DOCS IN NEUROBIOLOGY WHO
13 HAVE EXPERIENCE IN THINGS, BUT NOT IN PARTICULAR IN
14 THE DETAILED ASSAYS AND STUDIES THAT WERE
15 CONTEMPLATED. SO THAT IS PART OF IT.

16 ALSO, SOME OF THE EQUIPMENT THAT OBVIOUSLY
17 WOULD BE RESIDENT AT THE OTHER PLACE, BUT THAT'S A
18 SMALL PART. THAT'S ABOUT \$207,000, AND THERE'S SOME
19 VECTOR CORE CHARGES FOR SOME HISTOLOGY SERVICES AS
20 WELL TO HELP WITH SOME OF VECTORS FOR THE THIRD AIM.

21 SO THAT'S THE MAIN DRIVER. THOSE ARE THE
22 MAIN DRIVERS OF THE INCREASE IN DIRECT PROJECT COSTS
23 OVER THE COURSE OF THE AWARDS.

24 AS YOU KNOW, CIRM ALSO HAS COSTS CALLED
25 DIRECT FACILITIES COSTS, WHICH ARE ESSENTIALLY

BARRISTERS' REPORTING SERVICE

1 CALCULATED ON RESEARCH THAT'S DONE AT THE
2 INSTITUTION. OBVIOUSLY CIRM AND THE ICOC DOES NOT
3 WANT TO PAY DIRECT FACILITIES COSTS ON RESEARCH THAT
4 ARE CONDUCTED AT A NEIGHBORING INSTITUTION, AT
5 ANOTHER INSTITUTION WHETHER IT BE INSIDE CALIFORNIA
6 OR NOT. SO DIRECT COSTS ARE ALWAYS ADJUSTED FOR
7 COSTS THAT DO NOT OCCUR AT THE INSTITUTION. WHEN
8 YOU MOVE A LOT OF THE COSTS THAT WERE FORMERLY GOING
9 TO BE CONDUCTED OUTSIDE OF THE INSTITUTION INTO THE
10 INSTITUTION, YOU HAVE A BIGGER BASE FOR YOUR
11 CALCULATION OF DIRECT FACILITIES COST.

12 AND SO THAT'S WHY -- AND THEN THE INDIRECT
13 COST IS CALCULATED ON THE SUM OF DIRECT PROJECT
14 COSTS AND DIRECT FACILITIES COSTS, AND THAT'S JUST
15 FIXED BY THE RFA. THE DIRECT FACILITIES RATE IS A
16 NEGOTIATED RATE THAT EACH INSTITUTION HAS WITH THE
17 NIH THAT CIRM REVIEWS FOR THAT PORTION OF IT THAT'S
18 ALLOWABLE. SO IT IS -- WE DO THIS EVERY YEAR. WE
19 GO THROUGH WITH THE INSTITUTION WHAT THEIR CURRENT
20 DIRECT NEGOTIATED FACILITIES RATE IS WITH THE NIH,
21 AND THAT IS WHAT WE USE.

22 CHAIRMAN KLEIN: DR. OLSON, I THINK YOU'VE
23 DONE A TREMENDOUS JOB. IT DEMONSTRATES THE
24 DISCIPLINE OF OUR GRANT ADMINISTRATION POLICY THAT
25 ESSENTIALLY IDENTIFIED THIS ISSUE AND WORKED THROUGH

BARRISTERS' REPORTING SERVICE

1 THE PROBLEMS TO MAKE SURE WE BROUGHT IT INTO
2 COMPLETE COMPLIANCE WITH CALIFORNIA AND CALIFORNIA
3 REGULATIONS FOR PROPOSITION 71.

4 THE TOTAL INCREASED COSTS, I UNDERSTAND,
5 ARE 1,853,179 AS SHOWN ON YOUR SUMMARY; IS THAT
6 CORRECT?

7 DR. OLSON: THAT IS CORRECT.

8 CHAIRMAN KLEIN: SO THAT'S UP TO. THAT'S
9 VERY IMPORTANT.

10 DR. OLSON: THAT'S AN IMPORTANT POINT.

11 CHAIRMAN KLEIN: BECAUSE WE DO
12 ADMINISTRATIVELY HAVE ACUTELY FOCUSED OVERSIGHT
13 DURING THE COURSE OF THE RESEARCH.

14 I'D LIKE TO SEE IS THERE A MOTION TO
15 APPROVE?

16 MR. SHEEHY: SO MOVED.

17 DR. LOVE: SECOND.

18 CHAIRMAN KLEIN: SO MOVED BY JEFF SHEEHY,
19 SECOND BY DR. LOVE. IS THERE ADDITIONAL COMMENT BY
20 THE MEMBERS?

21 MS. SAMUELSON: YES, I HAVE COMMENT.

22 CHAIRMAN KLEIN: SO, JOAN, I'M GOING TO
23 LET YOU LEAD ON THESE -- JOAN, I'M GOING TO HAVE YOU
24 LEAD ON THESE COMMENTS, THEN I'M GOING TO GO TO
25 MICHAEL GOLDBERG, AND THEN I'M GOING TO GO TO DR.

BARRISTERS' REPORTING SERVICE

1 POMEROY, AND THEN I'M GOING TO GO TO THE UPPER TIER
2 AND THOSE COMMENTS.

3 NOTICE THE LEAD IS ON THE SPEARHEAD OF THE
4 ORGANIZATION THAT'S ON THE FRONT OF THIS
5 ORGANIZATION.

6 MS. SAMUELSON: THIS IS JOAN. IS THIS
7 DOABLE WITH THIS FEEDBACK? WHAT DO YOU THINK, BOB?
8 SHOULD I TRY THIS?

9 CHAIRMAN KLEIN: ABSOLUTELY TRY IT.

10 JOAN, MELISSA KING HAS SUGGESTED THAT IF I
11 GO AND START WITH MR. GOLDBERG, GO TO DR. POMEROY,
12 THAT MELISSA KING WILL TALK TO YOU, GET YOUR
13 COMMENTS, AND RELAY THEM. SHE'S GOING TO RELAY THEM
14 IN REAL-TIME. SO SHE'S GOING TO CONNECT WITH YOU
15 RIGHT NOW, GO OVER THEM, AND THEN IN REAL-TIME GO
16 THROUGH YOUR COMMENTS, SO WE CAN GET A CLEAR
17 UNDERSTANDING. MR. GOLDBERG AND THEN DR. POMEROY.

18 MR. GOLDBERG: COULD YOU PLEASE REMIND US,
19 FOR THE EARLY TRANSLATIONAL RESEARCH AWARDS, WHAT
20 THE UNUSED, IF THERE WAS UNUSED, FUNDING IN
21 CONNECTION WITH THAT GRANT COHORT?

22 DR. OLSON: ACTUALLY THE EARLY
23 TRANSLATIONAL RESEARCH AWARD, THIS BOARD AWARDED \$72
24 MILLION IN AWARDS, AND THE ORIGINAL ALLOCATION HAD
25 BEEN 60 MILLION, BUT THE BOARD WAS SO IMPRESSED BY

BARRISTERS' REPORTING SERVICE

1 THE QUALITY OF THE AWARDS -- OF THE APPLICATIONS
2 THAT CAME FORTH AT THAT TIME, THAT THEY INCREASED
3 THE ALLOCATION.

4 MR. GOLDBERG: COULD YOU REMIND US OF THE
5 PRIORITY SCORE FOR THIS SPECIFIC GRANT?

6 DR. OLSON: THIS WAS A TIER I APPLICATION.
7 IT HAD A 79, ACTUALLY. AND I THINK, AS IT WAS
8 INDICATED IN THE SUMMARY, THERE WAS A MOTION TO MOVE
9 IT EVEN HIGHER IN THE TIER, BUT THAT DID FAIL, BUT
10 THIS WAS A TIER I AWARD AS RECOMMENDED BY THE GRANTS
11 WORKING GROUP.

12 MR. GOLDBERG: THANK YOU.

13 CHAIRMAN KLEIN: THANK YOU. DR. POMEROY.

14 DR. POMEROY: SO I SUPPORTED FUNDING THIS
15 WHEN WE FUNDED IT, AND I DON'T THINK THAT THE ISSUES
16 ON THE TABLE ARE REALLY A REREVIEW OF THE IMPORTANCE
17 OF THIS GRANT. IT'S A VERY IMPORTANT GRANT.

18 MY COMMENTS ARE ABOUT THE PROCESS, AND
19 THAT'S WHERE I DO HAVE SOME CONCERN. AND IF A
20 PROPOSAL CAME IN THAT VIOLATED CIRM POLICIES, I
21 PRESUME THAT WE WOULD REVIEW THAT AND REJECT IT.
22 SAY THIS HAD BEEN TO DO THE WHOLE THING AT YALE.
23 THAT NEVER WOULD HAVE PROCEEDED THROUGH THIS
24 PROCESS.

25 SO THE FACT THAT WE DIDN'T CATCH THIS

BARRISTERS' REPORTING SERVICE

1 INITIALLY CONCERNS ME. AND THE REASON THAT THAT
2 CONCERNS ME IS BECAUSE THE GRANT REVIEWERS
3 PRESUMABLY PRESUMED THAT THESE SENIOR INVESTIGATORS
4 WOULD BE DOING THIS RESEARCH. AND PART OF THEIR
5 SCORE WAS RELATED TO THE FACT THE EXPERTISE OF THOSE
6 PEOPLE. AND I'M SURE THESE POST DOCS THAT YOU REFER
7 TO ARE VERY TALENTED PEOPLE, BUT THE GRANT SCORE MAY
8 HAVE BEEN DIFFERENT IF THEY HAD BEEN THE ONES
9 PROPOSED TO DO THIS.

10 THE OTHER COMMENT IS JUST A COMMENT ABOUT
11 HOW AN INSTITUTION RESPONDS WHEN THESE KIND OF
12 PROBLEMS ARISE. AND IN SOME CASES I THINK THAT
13 INSTITUTIONS WOULD WAIVE THEIR ADDITIONAL INDIRECT
14 COSTS TO ACCOMMODATE THE FACT THAT THIS CHANGE WAS
15 REQUIRED.

16 THOSE ARE MY COMMENTS ABOUT THE PROCESS
17 AND NOT ABOUT THE IMPORTANCE OF THIS GRANT.

18 CHAIRMAN KLEIN: THANK YOU. AND SO DR.
19 LEVIN AND THEN WE'VE GOT JEFF SHEEHY.

20 DR. TROUNSON: I WONDER IF I CAN JUST
21 RESPOND.

22 CHAIRMAN KLEIN: ABSOLUTELY. DR.
23 TROUNSON.

24 DR. TROUNSON: THAT'S WHY WE HAD A SENIOR
25 PERSON FROM THE AREA REVIEW THE CHANGES AND WENT

BARRISTERS' REPORTING SERVICE

1 THROUGH THOSE IN SOME DETAIL. AND I FELT THAT IT
2 WAS ALSO IMPORTANT FOR -- SO THAT'S WHY WE HAD AN
3 INDEPENDENT REVIEWER FROM THE PARKINSON'S AREA. AND
4 WE ALSO, IN ADDITION, DECIDED A SITE VISIT TO REALLY
5 LOOK AT THESE PEOPLE AND LOOK AT THE WHOLE PROGRAM
6 WAS WARRANTED.

7 AND THE LEAD PERSON FROM YALE IS ATTENDING
8 THE INSTITUTION ON A REGULAR BASIS, AND WE WERE
9 PRETTY CONVINCED REALLY BY HIS STRONG ARGUMENT THAT
10 THIS PROJECT WAS A FULL MERIT STILL. SO ALONG WITH
11 THE REVIEWER'S COMMENTS, WE FELT THAT IT REALLY
12 HADN'T DEPARTED DRAMATICALLY FROM THE PROJECT THAT
13 WE SAW IN THE FIRST INSTANCE.

14 CHAIRMAN KLEIN: SO DR. OLSON AND THEN I'M
15 GOING TO GO TO DR. LEVIN AND JEFF SHEEHY AND THEN
16 OVER TO SHERRY LANSING.

17 DR. OLSON: I WOULD LIKE TO RESPOND TO
18 CLAIRE'S FIRST COMMENT, WHICH I DO APPRECIATE. AND
19 I WANT TO RESPOND AS FOLLOWS: WHEN STAFF RECEIVES
20 APPLICATIONS, IN POINT OF FACT, WE DO DO A CHECK.
21 WE CHECK FOR PI ELIGIBILITY. WE CHECK FOR CO-PI
22 ELIGIBILITY. WE CHECK FOR INSTITUTIONAL
23 ELIGIBILITY. AND IDEALLY IN A WORLD OF UNLIMITED
24 RESOURCES AND MORE STAFF, WE WOULD CHECK FOR ALL
25 THESE PARAMETERS. WE DID NOT SEE THIS. I'M NOT

BARRISTERS' REPORTING SERVICE

1 SURE WE WOULD HAVE DISALLOWED IT. I DON'T KNOW THAT
2 WE WOULD HAVE. A LOT OF TIMES WE PUT THINGS THROUGH
3 TO THE WORKING GROUP. THEY THEN -- WE LET THEM
4 KNOW, AND THEY WERE AWARE. THIS WAS JUSTIFIED IN
5 THE BUDGET JUSTIFICATION.

6 AND WHEN THEY RAISED CONCERNS, SO THEY'VE
7 RAISED CONCERNS BEFORE, THEY'VE SAID, FOR AN
8 EXAMPLE, THIS PERSON'S SALARY SEEMS TO BE OVER THE
9 CAP. AND WE TELL THEM THAT WE WILL DEAL WITH THAT
10 IN PREFUNDING ADMINISTRATIVE REVIEW. SO THAT OUR
11 PROCESS IS IN THE PREFUNDING ADMINISTRATIVE REVIEW
12 TO CATCH SOME OF THESE THINGS. BUT AS I SAY,
13 IDEALLY IN THE BEST POSSIBLE WORLD, WE WOULD TRY --
14 WE WOULD READ ALL THE APPLICATIONS, WE WOULD CATCH
15 ALL OF THESE THINGS BEFORE WE MOVE FORWARD. BUT TO
16 HAVE A TURNAROUND TIME OF EIGHT WEEKS OR LESS FROM
17 THE TIME OF RECEIPT OF APPLICATIONS TILL A REVIEW
18 IMPOSES SOME CHALLENGES ON US.

19 CHAIRMAN KLEIN: I THINK THAT WE LEARN
20 CONSTANTLY, AND WE'VE TAKEN THE LESSONS, DR.
21 POMEROY, AND REALLY ENHANCED OUR PRECLEARANCE
22 CHECKLIST AS WELL.

23 ELONA BAUM, DID YOU HAVE A COMMENT?

24 MR. TORRES: WE HAVE 20 MINUTES BEFORE
25 WE'RE GOING TO LOSE SOME MEMBERS TO LEGISLATIVE

BARRISTERS' REPORTING SERVICE

1 VISITS.

2 MS. BAUM: IT'S VERY CRITICAL THAT I JUST
3 PUT THIS ON THE RECORD. I JUST WANT TO CLARIFY.
4 DR. OLSON SAID THAT IF SHE HAD KNOWN THAT THERE WAS
5 SOME OUT-OF-STATE FUNDING, THAT SHE WOULDN'T
6 NECESSARILY NOT ALLOW IT. I THINK WHAT SHE WAS
7 SAYING WAS NOT THAT -- THE POSITION IS IS THAT IT IS
8 ACCEPTABLE FOR US TO FUND RESEARCH OUTSIDE OF THE
9 STATE. SHE WOULD HAVE LET IT GONE FORWARD TO THE
10 GRANTS WORKING GROUP AND LET THEM KNOW THAT THIS WAS
11 AN ISSUE, AND IT WOULD BE A PLACE SO THAT THEY COULD
12 MAKE THE DECISION BASED ON THAT. I DIDN'T WANT ANY
13 OTHER -- I DIDN'T WANT ANYTHING ELSE DRAWN FROM THAT
14 STATEMENT.

15 CHAIRMAN KLEIN: SO I'D LIKE TO CALL ON
16 DR. LEVIN.

17 DR. LEVIN: THANKS. I'D LIKE TO, I GUESS,
18 SHARE CLAIRE'S CONCERNS. I'M TORN ON THIS GRANT.
19 IT'S CLEARLY A WONDERFUL PROJECT THAT HAS A LOT OF
20 POTENTIAL. IT'S A GREAT GROUP OF INSTITUTIONS THAT
21 COULD POTENTIALLY MAKE A REAL DIFFERENCE IN
22 ATTACKING PARKINSON'S. AND I'M ALSO AWARE OF THE
23 LARGE AMOUNT OF DILIGENCE THAT THE CIRM STAFF HAS
24 DONE IN DOING THE SITE VISITS AND MAKING SURE THAT
25 THIS PROJECT IS REASONABLY ASSURED OF SUCCESS HAD IT

BARRISTERS' REPORTING SERVICE

1 GONE IN THIS NEW FORM.

2 HOWEVER, I AM UNCOMFORTABLE WITH THE
3 PROCESS BECAUSE WE HAVE A VERY STRICT PROCESS THAT
4 WE MAKE ALL THE OTHER GRANT APPLICANTS ADHERE TO AND
5 THAT, I BELIEVE, IN MANY SITUATIONS GRANTS HAVE NOT
6 BEEN APPROVED BECAUSE THEY DON'T CONFORM TO THE GAP.
7 GRANTS WILL HAVE BEEN PULLED BACK WHEN THEY'RE NOT
8 MEETING THEIR MILESTONES IF THINGS LIKE THIS ARE
9 CAPABLE OF HAPPENING. EVERY OTHER APPLICANT TAKES
10 GREAT CARE TO ADHERE TO ALL OF OUR POLICIES. IT
11 SEEMS TO ME THAT THIS PROPOSAL DID NOT. AND WE'RE
12 NOT TALKING OF A SMALL CHANGE LIKE, OH, WE NEED A
13 CALIFORNIA VENDOR VERSUS. THIS IS MORE THAN
14 50-PERCENT INCREASE IN THE GRANT FUNDING LEVEL.
15 YOU'RE REPLACING, AS YOU STATED, THE SENIOR
16 EXPERIENCED INVESTIGATORS WITH INEXPERIENCED
17 INVESTIGATORS, WHICH IT'S NOT CLEAR WHY THAT WOULD
18 BE THREE TIMES THE PRICE SINCE THEY ARE USUALLY
19 CHEAPER, BUT IT RAISES SOME CONCERNS AS TO FOLLOWING
20 PROCESS.

21 IF WE ALLOW THIS TO GO FORWARD, THEN CAN
22 EVERYBODY COME BACK AND SAY, WELL, PROPOSE ONE THING
23 AND THEN CHANGE IT LATER AND WE'RE OPENING OURSELVES
24 UP TO A LOT OF LIABILITY IN THIS REGARD. AND
25 ESPECIALLY BECAUSE THE DIFFERENCE IN FUNDING LEVEL

BARRISTERS' REPORTING SERVICE

1 IS ENOUGH FOR AN ENTIRE OTHER GRANT.

2 SO I THINK WE NEED TO CONSIDER CAREFULLY
3 WHETHER WE'RE OKAY WITH THIS PROCESS REGARDLESS OF
4 WHETHER THE GRANT ITSELF IS GOING TO BE ABLE TO
5 ACHIEVE WHAT IT WANTED TO DO.

6 CHAIRMAN KLEIN: DR. TROUNSON, IS IT MY
7 UNDERSTANDING THAT THE PI FROM YALE HAS, IN FACT,
8 COMMITTED HIMSELF TO PARTICIPATING IN THIS AT
9 BURNHAM IN TERMS OF ADVISING THEM? IS THAT A
10 CORRECT STATEMENT?

11 DR. TROUNSON: THAT'S CORRECT. THAT IS
12 ABSOLUTELY CORRECT. DR. REDMAN, WHO IS THE KEY AT
13 YALE, IS A TERRIFIC SCIENTIST. AND HE WAS THERE AT
14 THE ON-SITE MEETING, AND HE GAVE ABSOLUTE SUPPORT.
15 IN FACT, THERE ARE -- A SENIOR MEMBER OF HIS TEAM IS
16 ACTUALLY MOVING TO THE BURNHAM. SO ONE OF THOSE
17 PERSONS WHO WOULD HAVE BEEN DOING THIS AND KEY IN
18 THE PROJECT WILL ACTUALLY BE MOVING THERE.

19 SO I ACTUALLY FEEL THAT THIS PROJECT IS
20 COMPOSED IN A WAY THAT WE WOULD RANK IT IN THAT AREA
21 IF WE SAW IT AGAIN AS IT IS NOW. AND I BELIEVE THAT
22 THERE'S NO REAL REASON TO PUT A SUBSTANTIAL DELAY IN
23 TURNING IT BACK THROUGH. IT WILL HAVE TO BE QUITE A
24 DISTANCE NOW FOR IT TO COME UP AGAIN IN ANOTHER
25 TRANSLATIONAL PROGRAM. IT WILL BE MORE THAN 12

BARRISTERS' REPORTING SERVICE

1 MONTHS AWAY BEFORE THEY CAN APPLY AGAIN.

2 CHAIRMAN KLEIN: THANK YOU. IS JOAN
3 READY, AND THEN WE'RE GOING TO GO TO JEFF.

4 MS. SAMUELSON: SURE. ALTHOUGH I HAVE TO
5 SAY, BOB, I'M WONDERING IF WE'RE NOW UP AGAINST --

6 CHAIRMAN KLEIN: JOAN, CAN YOU HEAR US
7 NOW? HOW IS YOUR TRANSMISSION AT THIS POINT? NOT
8 GOOD. JEFF SHEEHY AND THEN WE HAVE SHERRY LANSING
9 AND THEN DAVID SERRANO-SEWELL.

10 MR. SHEEHY: I'M HEARING A LOT HERE ABOUT
11 PROCESS. AND, YOU KNOW, LET'S JUST BE CLEAR. THIS
12 IS INCREDIBLY IMPORTANT SCIENCE. AND WHEN YOU LOOK
13 AT THE TRANSLATION DISEASE TEAM SPACE, THIS IS
14 REALLY THE KEY PARKINSON'S GRANT. THERE'S NO
15 PARKINSON'S GRANT IN THE DISEASE TEAM SPACE.

16 LET'S THINK ABOUT WHAT THE SCIENCE IS HERE
17 AND WHAT WE'RE TALKING ABOUT. THE RESOURCE THAT WE
18 ARE HAVING TROUBLE ACCESSING THAT IS THE SOURCE OF
19 THE PROBLEM IS A UNIQUE RESOURCE. WE TALKED ABOUT
20 THIS AT THE STANDARDS WORKING GROUP. WE TALKED
21 ABOUT THIS MANY TIMES, THAT THERE'S NO GOOD DISEASE
22 MODELS FOR PARKINSON'S. AND THIS PARTICULAR ANIMAL
23 MODEL THAT WE'RE HAVING TO RESOURCE OUTSIDE OF
24 CALIFORNIA IS THE ABSOLUTE BEST ANIMAL MODEL FOR
25 PARKINSON'S. IT'S STATE OF THE ART.

BARRISTERS' REPORTING SERVICE

1 THE GOAL OF THIS RFA IS TO SEE WHICH
2 CELLS, WHETHER EMBRYONIC, IPS, MESENCHYMAL, THEY
3 HAVE A WHOLE BASKET OF CELLS THAT THEY'RE GOING TO
4 TEST IN THIS ANIMAL MODEL TO SEE WHICH IS GOING TO
5 BE MOST EFFECTIVE AT PRODUCING DOPAMINERGIC NEURONS
6 TO CURE OR POTENTIALLY CURE PARKINSON'S. THIS IS A
7 CRITICAL PART OF OUR MISSION. THIS IS A CRITICAL
8 PART OF MOVING FORWARD IN THE FIGHT AGAINST
9 PARKINSON'S.

10 AND WE CAN GET INTO THE WEEDS ON PROCESS,
11 BUT WE'RE A NEW AGENCY. AND THIS WAS OUR FIRST
12 EARLY TRANSLATION ROUND. YOU GUYS ARE AMAZING.
13 IN A WAY WE'RE HAVING TO DISCOVER THINGS AS WE GO
14 ALONG. SO IF WE SIT HERE AND BOG OURSELVES DOWN ON
15 PROCESS, WHO ARE WE REALLY HELPING? I HAVE ABSOLUTE
16 CONFIDENCE IN THE DISCRETION OF THE PRESIDENT, WHICH
17 WE HAVE -- WE'VE BEEN EMPHATIC ALL THE ALONG IN
18 GIVING THE PRESIDENT DISCRETION WHEN THERE ARE
19 PROBLEMS WITH GRANTS TO RESOLVE THEM.

20 WE HAD ANOTHER GRANT, THE JACKSON LABS
21 GRANT, IN THE SAME ROUND THAT WE GAVE ENORMOUS
22 AMOUNT OF DISCRETION TO THE PRESIDENT AND TO STAFF
23 TO MAKE THAT WORK ACCORDING TO ISSUES RAISED BY THE
24 REVIEWERS. I DON'T THINK THAT THE ISSUE OF HAVING
25 TO ACCESS AND MANAGE THIS ANIMAL RESOURCE IS ANY WAY

BARRISTERS' REPORTING SERVICE

1 NEGATIVELY IMPACTED BY THIS SHIFT. THE KEY SCIENCE
2 IS BEING DONE AT THE BURNHAM, WHICH IS THE
3 INSTITUTE.

4 IT WAS A HIGH SCORING GRANT. IT'S VERY
5 INNOVATIVE. IT'S KEY TO MOVING FORWARD. I DON'T
6 SEE HOW WE CAN TELL PEOPLE IN THE PARKINSON'S
7 COMMUNITY, BECAUSE WE WERE HAVING TO MANAGE OUR
8 PROCESS, BECAUSE WE HAVE A RELATIVELY SMALL STAFF
9 WORKING, YOU KNOW, 9,000 MILES AN HOUR, WE'RE GOING
10 TO BE DOING CLINICAL TRIALS, THAT SOMEHOW WE
11 COULDN'T PUT ALL THE PIECES TOGETHER TO REALLY GET
12 THIS TO WORK. NOW THAT WE'VE FIGURED IT OUT, WE'RE
13 GOING FOR IT. AND THE IDEA THAT SOMEHOW SOME OTHER
14 SCIENTIST WAS PENALIZED BY NOT HAVING THEIR GRANT,
15 AS WAS REPORTED ON THE BLOG, THAT SOME OTHER
16 SCIENTIST DIDN'T GET THEIR GRANT. AS PER MICHAEL
17 GOLDBERG'S QUESTION, WE WENT OUTSIDE THE RANGE. WE
18 CAN ALWAYS GO OUTSIDE THE RANGE. WE COULD HAVE
19 APPROVED ANY NUMBER OF ADDITIONAL GRANTS, SO IT
20 WASN'T LIKE THIS DISPLACED ANOTHER GRANT.

21 WE WERE COMMITTED TO THE SCIENCE. WE WERE
22 COMMITTED TO MAKING A DIFFERENCE IN PARKINSON'S
23 DISEASE. I DON'T SEE HOW -- YOU KNOW, THAT THIS
24 PRESENTS ANY PROBLEM. I ALSO NOTE THAT THIS WAS A
25 \$6 MILLION POTENTIAL ROUND PER AWARD, SO THEY'RE

BARRISTERS' REPORTING SERVICE

1 WELL -- THEY'RE STILL BELOW AND WE HAD A LOT OF
2 PEOPLE GO ALL THE WAY TO SIX MILLION IN THIS ROUND.

3 CHAIRMAN KLEIN: SO, JEFF, THANK YOU. AND
4 JUST FOR THE RECORD, I WANT TO REMIND EVERYONE WHO'S
5 LISTENING THAT JEFF HAS A RECORD OF BEING COMPLETELY
6 COMMITTED TO PROCESS. I THINK WHAT I UNDERSTAND YOU
7 TO SAY IS THAT SINCE THE PROCESS, IN FACT, INCLUDES
8 THE GRANTS ADMINISTRATION PROGRAM THAT IS INTENDED
9 TO CATCH AND DEAL WITH ISSUES LIKE THIS, THAT IS
10 EXACTLY WHAT IT DID AND IT BROUGHT IT COMPLETELY
11 INTO COMPLIANCE.

12 THE FACT THAT WE CAN IMPROVE IS VERY
13 IMPORTANT, AND WE ARE ALWAYS COMMITTED TO IMPROVING
14 AND FOLLOWING MORE DETAILED CHECKLISTS. AS WE GAIN
15 STAFF, WE'RE ABLE TO DRILL DEEPER DOWN INTO THIS.
16 THE ISSUE HERE IS THAT THOSE PROCESS ISSUES HAVE
17 FROM THE PRESIDENT'S VIEWPOINT BEEN ADDRESSED.

18 BUT, SHERRY, IF YOU WOULD --

19 DR. POMEROY: MAY I RESPOND?

20 CHAIRMAN KLEIN: DR. POMEROY AND THEN
21 WE'RE GOING TO HAVE JOAN. DR. POMEROY.

22 DR. POMEROY: I WANT TO REASSURE JEFF THAT
23 MY COMMENT WAS NOT MEANT TO SUGGEST THAT WE SHOULD
24 PULL THIS GRANT IN ANY WAY. MY COMMENT WAS MEANT TO
25 SUGGEST THAT THE FACT THAT IT COST \$1.8 MILLION MORE

BARRISTERS' REPORTING SERVICE

1 TO DO THIS AT BURNHAM THAN IT DID AT YALE SUGGESTS
2 TO ME THAT WE SHOULD CONSIDER THE INSTITUTION
3 SHARING SOME OF THE FINANCIAL HIT THAT IS ASSOCIATED
4 WITH THIS CHANGE.

5 MS. KING: MS. SAMUELSON'S COMMENTS.

6 CHAIRMAN KLEIN: YES. JOAN SAMUELSON,
7 PLEASE.

8 MS. KING: CAN YOU HEAR ME? WE CAN HEAR
9 YOU, SO WHY DON'T YOU TRY AND MAKE THEM YOURSELF AND
10 I'M HERE AS A BACKUP.

11 MS. SAMUELSON: I ENTHUSIASTICALLY SUPPORT
12 THE GRANT PROPOSAL. ONE WAY OR ANOTHER I THINK THIS
13 NEEDS TO BE FUNDED. CAN YOU UNDERSTAND ME?

14 CHAIRMAN KLEIN: SO, JOAN, WE'RE GOING TO
15 HAVE MELISSA REPEAT YOUR STATEMENTS IN REAL-TIME.

16 MS. KING: CORRECT ME IF I'M WRONG, BUT
17 THIS IS WHAT I UNDERSTOOD YOU TO TELL ME BEFORE.
18 YOU ENTHUSIASTICALLY SUPPORT THIS GRANT; HOWEVER,
19 YOU FEEL THAT THERE ARE SOME HIGHLY IMPORTANT ISSUES
20 BEING RAISED IN THIS CONVERSATION. AND YOU DON'T
21 WANT THOSE TO BE LOST AND YOU DON'T WANT THE
22 DISCUSSION ON THOSE TO END WITH THIS VOTE.

23 THEREFORE, YOU'D LIKE TO ACTUALLY MAKE A
24 MOTION TO APPROVE THIS GRANT AS PRESENTED BY DR.
25 OLSON WITH THE UNDERSTANDING THAT THE BOARD, AS PART

BARRISTERS' REPORTING SERVICE

1 OF THAT MOTION, DIRECTING STAFF TO WORK WITH THE
2 BOARD TO CONTINUE THE DISCUSSION OF THE NUMEROUS
3 ISSUES THAT WERE RAISED IN THE DISCUSSION.

4 MS. SAMUELSON: THAT'S CORRECT.

5 CHAIRMAN KLEIN: ALL RIGHT. IS THERE A
6 SECOND TO THAT MOTION?

7 DR. PRIETO: SECOND.

8 CHAIRMAN KLEIN: SECOND FROM DR. PRIETO.
9 WE ALREADY HAVE A SEPARATE MOTION PENDING. AND SO
10 LET ME ASK WHO MADE THE ORIGINAL MOTION?

11 JEFF, WOULD YOU ACCEPT THAT AMENDMENT FROM
12 JOAN? HER AMENDMENT WAS THAT THE DISCUSSION OF
13 THESE ISSUES THAT HAVE BEEN RAISED NOT STOP WITH
14 THIS VOTE, BUT THE STAFF WILL WORK WITH THE BOARD TO
15 CONTINUE TO TRY AND ACHIEVE THE INTENT OF THE
16 COMMENTS THAT HAVE BEEN MADE.

17 DR. TROUNSON: I DON'T THINK IT'S GOING TO
18 CHANGE ANYTHING. TO BE HONEST, WE'VE GOT THE BEST
19 DEAL THAT IS POSSIBLE.

20 CHAIRMAN KLEIN: I DON'T THINK THEY'RE
21 ASKING THAT YOU -- THEY'RE TALKING ABOUT ADDRESSING
22 PROCESS, NOT CHANGING THIS GRANT FURTHER, DR.
23 TROUNSON.

24 DR. TROUNSON: I THINK -- LET ME JUST SAY
25 WITH THE QUANTUM OF MONEY THAT'S NECESSARY TO

BARRISTERS' REPORTING SERVICE

1 UNDERTAKE THE PROJECT, WITHOUT THAT QUANTUM OF
2 MONEY, THEY CAN'T DO IT.

3 CHAIRMAN KLEIN: OKAY. DR. TROUNSON, HER
4 MOTION WAS TO APPROVE THIS, BUT HAVE THE BOARD
5 MEMBERS WORK WITH THE STAFF TO TRY AND ADDRESS
6 PROCESS ISSUES.

7 THE MAKERS OF THE MOTION AND THE SECOND
8 HAVE ACCEPTED THE MODIFICATION. SHERRY LANSING, YOU
9 HAVE THE FLOOR.

10 MS. LANSING: I ALWAYS BELIEVE WE SHOULD
11 DO WHAT'S IN THE BEST INTEREST OF THE SCIENCE AND OF
12 THE PATIENTS. SO I HAVE A REALLY NAIVE QUESTION TO
13 ASK. CAN YOU EXPLAIN TO ME WHY IT CAN'T BE
14 RESUBMITTED AND THEN GONE THROUGH AND HOW LONG THAT
15 PROCESS WOULD TAKE AND HOW THAT WOULD HARM US?

16 DR. TROUNSON: WELL, WE HAVE AN EARLY
17 TRANSLATIONAL PROGRAM WHICH THEY WOULD MISS OUT ON.

18 MS. LANSING: WHY? BECAUSE IT'S A WEEK
19 FROM NOW. WHY COULDN'T THEY JUST PUT THIS IN RIGHT
20 NOW?

21 DR. TROUNSON: WELL, I HAVEN'T ASKED THEM
22 TO DO THAT. I DON'T KNOW IF THEY WOULD ACTUALLY
23 MEET THOSE DEADLINES. I THINK THAT'S POSSIBLY
24 UNLIKELY THAT THEY WOULD DO IT. ANYWAY, THAT WILL
25 PUT THEM OFF. THERE WILL BE ANOTHER SEVEN MONTHS

BARRISTERS' REPORTING SERVICE

1 BEFORE IT WAS APPROVED. SO THEN THEY'RE LOOKING AT
2 ABOUT TEN MONTHS BEFORE THEY GO AGAIN. IF THEY
3 ACTUALLY MISS THIS DEADLINE, AND I'D HAVE TO TAKE
4 LEGAL ADVICE ON WHAT THEY COULD PUT IN BECAUSE IT
5 COULDN'T BE THE ORIGINAL ONE. IT'D HAVE TO BE THE
6 REVAMPED --

7 MS. LANSING: WHY COULDN'T IT BE? BECAUSE
8 THAT'S AGAINST OUR --

9 DR. TROUNSON: BECAUSE THE ORIGINAL ONE
10 HAS GOT THE YALE.

11 MS. LANSING: THIS NEW ONE THAT YOU HAVE,
12 IF YOU PUT IT IN -- IF IT'S DONE, WHY CAN'T THEY
13 JUST PUT IT IN?

14 DR. TROUNSON: I THINK IT WOULD BE AT
15 LEAST SEVEN MONTHS BEFORE IT WAS APPROVED, TEN
16 MONTHS BEFORE IT WAS UNDER WAY. I THINK THAT'S A
17 SIGNIFICANT LOSS IN A PROJECT WHICH I THINK IS FOR
18 PRIME TIME ALREADY. IT'S THERE. IT'S NOT GOING TO
19 CHANGE BECAUSE OF THIS. ALL WE'RE SAYING IS THAT
20 THEY INAPPROPRIATELY PUT SOME RESEARCH IN AT THE
21 YALE UNIVERSITY. THEY SHOULD HAVE READ THAT. OKAY.
22 WE PICKED IT UP AND WE'VE REFORMATTED IT TO SAY,
23 OKAY, YOU PUT THAT RESEARCH COMPONENT BACK IN THE
24 BURNHAM, AND I'LL MAKE A RECOMMENDATION, WHICH I'M
25 MAKING THROUGH PAT OLSON, TO YOU TO FUND IT NOW.

BARRISTERS' REPORTING SERVICE

1 I BELIEVE THE PROJECT IS AS GOOD AS WHAT
2 IT WAS WHEN IT WAS IN FRONT OF THE GRANTS WORKING
3 GROUP. I DON'T BELIEVE THERE'S ANY MERIT IN
4 DELAYING THE PROJECT. I DON'T THINK THE PROJECT
5 WILL CHANGE WITH ANY DELAY. I THINK WE'VE UNDERGONE
6 ALL THE PROCESSES THAT WERE BUILT INTO THE AGENCY,
7 AND WE PICKED UP THE ERROR. ARGUABLY IT MIGHT HAVE
8 BEEN SEEN BY THE INSTITUTION WHEN THEY PUT IT IN.
9 WE MIGHT HAVE PICKED IT UP A LITTLE EARLIER IN THE
10 PROCESS. YOU COULD ARGUE THAT WE NEED TO BE A BIT
11 MORE VIGILANT.

12 MS. LANSING: WHAT DO YOU THINK THE
13 CHANCES ARE OF BURNHAM PICKING UP THE OTHER COSTS
14 THAT THIS IS COSTING?

15 DR. TROUNSON: NONE. I THINK IT'S ZERO
16 CHANCE THAT THEY WILL PICK IT UP. WE HAD THOSE
17 DISCUSSIONS WITH THE BURNHAM INSTITUTE. AND THIS
18 WAS -- WE'VE CUT THEM -- THEY HAD PUT MORE INTO THIS
19 THAN IS IN FRONT OF YOU, AND WE CUT THEM BACK AND
20 SAID THAT WAS INAPPROPRIATE. WE WANTED TO CUT IT
21 DOWN TO THE ABSOLUTE MINIMUM TO MAKE THIS PROJECT
22 WORK AT THE SAME LEVEL AS IT WAS WHEN IT WAS --

23 MS. LANSING: ONE LAST QUESTION. THE
24 ONLY -- THE THING THAT BOTHERS ME, AND, AGAIN, I
25 NEVER WANT THE PROCESS TO INTERFERE WITH THE

BARRISTERS' REPORTING SERVICE

1 SCIENCE, BUT THE THING THAT BOTHERS ME, SINCE I AM A
2 PROCESS ORIENTED PERSON, IS WERE THERE OTHER THINGS
3 THAT PEOPLE DIDN'T APPLY BECAUSE THEY WERE
4 OUT-OF-STATE? ARE WE MAKING AN EXCEPTION THAT WE
5 COULD HAVE MADE FOR OTHER GRANTS AS WELL, ONLY THIS
6 CAME?

7 DR. TROUNSON: IT'S UNUSUAL THAT A MODEL
8 LIKE THIS IS OUT OF THE STATE. AND THE PEOPLE WHO
9 DEvised AND CREATED THIS MODEL WERE FROM YALE, SO
10 THEY HAVE A BIG -- BECAUSE THEY DEVELOPED IT OVER 25
11 YEARS, THEY HAVE REALLY BIG INPUT INTO IT. SO --

12 CHAIRMAN KLEIN: DR. TROUNSON, WE'RE ABOUT
13 TO LOSE OUR QUORUM. AND SO WE'VE HAD A VERY VIBRANT
14 DISCUSSION HERE.

15 MS. LANSING: WOULD IT HAVE BEEN RATED
16 DIFFERENTLY WITH LESSER PI'S?

17 DR. TROUNSON: OUR FEELING, AND INCLUDING
18 THAT OF THE INDEPENDENT ASSESSOR, WAS IT WOULD BE
19 RANKED THE SAME.

20 CHAIRMAN KLEIN: MY UNDERSTANDING, SHERRY,
21 IS THAT THE PI FROM YALE HAS COMMITTED HIMSELF TO
22 BEING ON-SITE AT BURNHAM TO PARTICIPATE.

23 SO I NEED TO CALL THIS QUESTION. AND THEN
24 WE'RE GOING TO HAVE A ROLL CALL ON THE AUDIO
25 PARTICIPATION.

BARRISTERS' REPORTING SERVICE

1 MS. KING: WE RECOMMEND THAT WE DO A FULL
2 ROLL CALL FOR THIS ITEM.

3 CHAIRMAN KLEIN: FINE. WE'RE FOLLOWING
4 THAT RECOMMENDATION. THOSE MEMBERS WITH CONFLICTS
5 WILL NOT BE CALLED. IF WE WILL START THE ROLL CALL,
6 PLEASE, AFTER PUBLIC COMMENT. SEEING NO PUBLIC
7 COMMENT, IF WE COULD COMMENCE THE ROLL CALL, PLEASE.

8 MS. KING: DONALD DAFOE FOR RICARDO AZZIZ.

9 DR. DAFOE: AYE.

10 MS. KING: GORDON GILL FOR DAVID BRENNER.

11 DR. GILL: AYE.

12 MS. KING: KIM WITMER FOR WILLIAM BRODY.

13 DR. WITMER: AYE.

14 MS. KING: JACOB LEVIN FOR SUSAN BRYANT.

15 DR. LEVIN: NO.

16 MS. KING: MICHAEL FRIEDMAN.

17 DR. FRIEDMAN: YES.

18 MS. KING: LEEZA GIBBONS.

19 MS. GIBBONS: YES.

20 MS. KING: MICHAEL GOLDBERG.

21 MR. GOLDBERG: YES.

22 MS. KING: SAM HAWGOOD.

23 DR. HAWGOOD: YES.

24 MS. KING: BOB KLEIN.

25 CHAIRMAN KLEIN: YES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: SHERRY LANSING.
2 MS. LANSING: I'M SO CONFUSED.
3 MS. KING: I WILL COME BACK TO YOU, MS.
4 LANSING. TED LOVE.
5 DR. LOVE: YES.
6 MS. KING: CLAIRE POMEROY.
7 DR. POMEROY: YES.
8 MS. KING: FRANCISCO PRIETO.
9 DR. PRIETO: (NO AUDIBLE RESPONSE.)
10 MS. KING: CARMEN PULIAFITO.
11 DR. PULIAFITO: YES.
12 MS. KING: ROBERT QUINT.
13 DR. QUINT: YES.
14 MS. KING: DUANE ROTH.
15 MR. ROTH: YES.
16 MS. KING: JOAN SAMUELSON.
17 MS. SAMUELSON: YES.
18 MS. KING: DAVID SERRANO-SEWELL.
19 MR. SERRANO-SEWELL: YES.
20 MS. KING: JEFF SHEEHY.
21 MR. SHEEHY: YES.
22 MS. KING: JONATHAN SHESTACK.
23 MR. SHESTACK: YES.
24 MS. KING: OSWALD STEWARD.
25 CHAIRMAN KLEIN: IF YOU THINK YOU ARE

BARRISTERS' REPORTING SERVICE

1 ABSTAINED, PLEASE.

2 MS. KING: ART TORRES.

3 MR. TORRES: AYE.

4 MS. KING: AND SHERRY LANSING.

5 MS. LANSING: YOU DON'T NEED MY VOTE, SO
6 I'M ABSTAINING.

7 CHAIRMAN KLEIN: SHE'S ABSTAINING.

8 MS. LANSING: I'M SO CONFUSED.

9 CHAIRMAN KLEIN: THE MEMBER IS ABSTAINING.
10 AND DUANE ROTH HAS A COMMENT.

11 MR. ROTH: I DIDN'T GET INVOLVED IN THE
12 DISCUSSION, BUT I WOULD LIKE TO ASK THAT WE REALLY
13 GO BACK AND LOOK CAREFULLY AT WHAT HAPPENED HERE
14 BECAUSE MY RECOLLECTION IS QUITE DIFFERENT IN HOW
15 THIS WAS PRESENTED. AND I'D LIKE YOU TO JUST COME
16 BACK AND MAYBE AT THE NEXT MEETING YOU CAN UPDATE
17 US. MY RECOLLECTION IS THAT THE TWO OUTSIDE
18 RESOURCES WERE TIED AS ONE, AND THAT'S WHY -- AND
19 THEN THE PIECE THAT WAS EVENTUALLY LOOKED AT SAID,
20 WELL, THIS MAY NOT PERFECTLY FIT OUR REQUIREMENTS,
21 BUT I DON'T THINK THERE WAS AN INTENTION TO SLIP
22 RESEARCH INTO THIS PROPOSAL. IT WAS THAT THE TWO
23 ORGANIZATIONS, ONE DIRECTLY TIED TO THE OTHER, WERE
24 LOOKED AT AS AN EXTERNAL CONTRACT ALMOST. AND
25 THAT'S WHY THE CONFUSION. IT WASN'T THAT WE MISSED

BARRISTERS' REPORTING SERVICE

1 SOMETHING. IT WAS WHETHER, IN FACT, THAT PORTION --
2 DR. TROUNSON: THAT'S CORRECT. IT WAS --
3 IT DID CONTAIN A SERVICE CONTRACT THAT COULD BE
4 SEPARATE.

5 CHAIRMAN KLEIN: I THINK WHAT DUANE ROTH
6 IS SAYING IS IT WAS DIFFICULT TO ANALYZE HOW MUCH
7 WAS A SERVICE CONTRACT AND WHAT WAS RESEARCH, AND IT
8 WAS TIED TO THE ANIMAL MODEL. SO IT MADE IT VERY
9 COMPLEX TO SURGICALLY SEPARATE IT.

10 WHAT I'D LIKE TO DO HERE IS WE HAVE VERY
11 IMPORTANT -- MR. HARRISON WOULD LIKE TO MAKE A
12 STATEMENT. ART TORRES NEEDS TO GIVE US A BRIEFING
13 HERE, AND THEN WE NEED TO ADJOURN TO AN EXECUTIVE
14 SESSION. WE HAVE PEOPLE THAT NEED TO LEAVE TO GO TO
15 CERTAIN MEETINGS. MR. HARRISON.

16 MR. HARRISON: FOR THE RECORD, THAT MOTION
17 CARRIED WITH 19 YES VOTES.

18 MS. LANSING: MY CONFUSION, AND THAT'S THE
19 ONLY WORD I WOULD USE, SO VOTE CONFUSED, WHATEVER
20 YOU WANT TO SAY, WAS REALLY JUST ABOUT HOW THIS
21 HAPPENED. AND I LISTENED AND I REALLY WELCOME WHAT
22 DUANE IS SAYING. THE SCIENCE SOUNDS EXTRAORDINARY
23 AND I'M REALLY HAPPY THAT IT PASSED, BUT I JUST
24 DON'T UNDERSTAND IT. I WOULD REALLY APPRECIATE
25 THAT. YOU DON'T HAVE TO DO IT FOR THE FULL BOARD.

BARRISTERS' REPORTING SERVICE

1 MAYBE YOU COULD JUST DO IT FOR ME.

2 CHAIRMAN KLEIN: AND WE APPRECIATE THE --
3 I KNOW ALL OF US APPRECIATE THE ROBUST PARTICIPATION
4 OF ALL THE OTHER MEMBERS IN THIS PROCESS.

5 ART, YOU HAVE THE FLOOR. WE'RE GOING TO
6 LOOK AT THE LEGISLATIVE ITEM ON THE AGENDA, WHICH IS
7 ITEM 10.

8 MR. TORRES: THANK YOU, MR. CHAIRMAN AND
9 MEMBERS. IF YOU WOULD LOOK AT THE ITEM, WHICH IS
10 SENATE BILL 1064 BY SENATOR ALQUIST, I WOULD LIKE TO
11 HAVE MR. HARRISON GO OVER VERY QUICKLY BECAUSE I
12 THINK MOST OF THE MEMBERS KNOW WHAT'S IN THE BILL.
13 I THINK JUST A GENERAL OVERVIEW, MR. HARRISON, WOULD
14 BE MORE THAN APPROPRIATE.

15 MR. HARRISON: GOOD AFTERNOON, EVERYONE.
16 SENATE BILL 1064, AS VICE CHAIR TORRES SAID, DOES A
17 NUMBER OF THINGS. SO LET ME JUST BRIEFLY SUMMARIZE
18 THEM.

19 FOUR OF THE PROPOSALS THAT ARE MADE WITHIN
20 SB 1064 WERE ITEMS THAT CIRM ALREADY HAS UNDERTAKEN.
21 SO, FOR EXAMPLE, SB 1064 WOULD REQUIRE THE AGENCY TO
22 POST TALLIES WITH SUMMARIES OF THE VOTES AND
23 RECUSALS FOR ALL BOARD MEETINGS. SINCE THE VERY
24 FIRST MEETING OF THIS AGENCY, ALL OF THE MEETINGS
25 HAVE BEEN TRANSCRIBED AND THEN POSTED ON THE WEB

BARRISTERS' REPORTING SERVICE

1 SITE IMMEDIATELY UPON BEING AVAILABLE. AND GOING
2 BACK TO JANUARY 1, 2008, WE HAVE INCLUDED AS AN
3 ATTACHMENT TO THE MINUTES A SUMMARY OF THE VOTE
4 TALLIES AND RECUSALS.

5 LIKewise, 1064 WOULD REQUIRE US TO ENGAGE
6 IN SUCCESSION PLANNING. THE EVALUATION
7 SUBCOMMITTEE, WHICH IS SCHEDULED TO MEET ON MARCH
8 19TH, HAS ON ITS AGENDA, AMONG OTHER ITEMS, A
9 DISCUSSION OF SUCCESSION PLANNING.

10 1064 WOULD ALSO REQUIRE THAT ANY REVENUE,
11 ANY I.T. REVENUE, GENERATED FROM CIRM-FUNDED
12 RESEARCH WOULD BE DEPOSITED INTO THE GENERAL FUND OF
13 THE STATE OF CALIFORNIA. CIRM REGULATIONS ALREADY
14 REQUIRE THIS.

15 LIKewise, 1064 WOULD REQUIRE THE AGENCY TO
16 ENGAGE IN TRANSITION PLANNING RELATING TO THE
17 EXPIRATION OF BOND FUNDING THAT PRESIDENT TROUNSON
18 MENTIONED EARLIER; AND AS MENTIONED IN THE PAST, WE
19 HAVE BEEN ENGAGED IN THAT PROCESS FOR SOME TIME,
20 INCLUDING THE LOAN PROGRAM, THE DISCUSSION OF
21 FEDERAL LOAN GUARANTEES, AND OTHER OPTIONS FOR
22 EXTENDING CIRM'S FUNDING.

23 THERE ARE ADDITIONAL AREAS ADDRESSED IN
24 1064 WHICH I WILL JUST BRIEFLY NOTE. 1064 WOULD
25 REDUCE THE TERMS OF THE CHAIR AND VICE CHAIR FROM

BARRISTERS' REPORTING SERVICE

1 SIX YEARS TO FOUR YEARS AND REQUIRE THAT THEY BE
2 STAGGERED, BUT IT PROVIDES NO MECHANISM FOR GETTING
3 THEM TO THE POINT WHERE THEY'RE STAGGERED.
4 CURRENTLY THE CHAIR AND VICE CHAIR SERVE CONSECUTIVE
5 TERMS.

6 LIKewise, IT WOULD EXTEND THE JURISDICTION
7 OF THE CITIZENS FINANCIAL ACCOUNTABILITY OVERSIGHT
8 COMMITTEE TO INCLUDE A REQUIREMENT THAT THE
9 CONTROLLER ANNUALLY COMMISSION AN AUDIT, A
10 PERFORMANCE AUDIT, OF CIRM THAT EXAMINES ALL OF THE
11 AGENCY'S POLICIES, PRACTICES, AND PROCEDURES TO
12 DETERMINE WHETHER THEY'RE CONSISTENT WITH EXISTING
13 LAW AND WHETHER THEY COMPLIED. AS YOU ALL KNOW, THE
14 AGENCY HAS ALREADY BEEN SUBJECT TO SEVERAL AUDITS,
15 INCLUDING FROM THE BUREAU OF STATE AUDITS AND THE
16 CONTROLLER, AND WENT THROUGH THOSE WITH FLYING
17 COLORS.

18 AND FURTHERMORE, AS WAS MENTIONED EARLIER,
19 THE AGENCY IS IN THE PROCESS OF COMMISSIONING AN
20 EXTERNAL SCIENTIFIC REVIEW. SO TO IMPOSE ANOTHER
21 PERFORMANCE AUDIT ON TOP OF THE AUDITS THAT CIRM IS
22 ALREADY SUBJECT TO WOULD OBVIOUSLY INVOLVE
23 ADDITIONAL COST OF BSA AUDITS PLUS \$200,000 FOR BSA
24 TO CONDUCT AND ANOTHER 200,000 OF CIRM FUNDS AS WELL
25 AS THE INCREDIBLE AMOUNT OF STAFF TIME THAT REALLY

BARRISTERS' REPORTING SERVICE

1 DISTRACTS THE STAFF FROM FOCUSING ON THE AGENCY'S
2 CRITICAL MISSION.

3 THE BILL ALSO PROPOSES TO REALLOCATE SOME
4 OF THE DUTIES OF THE CHAIR TO THE PRESIDENT.
5 SPECIFICALLY IT WOULD ELIMINATE THE CHAIR'S
6 RESPONSIBILITY ON BEHALF OF THE BOARD FOR PROVIDING
7 OVERSIGHT OF THE AGENCY'S COMPLIANCE WITH PUBLIC
8 ACCOUNTABILITY LAWS, CONFLICT OF INTEREST LAWS,
9 PUBLIC MEETING LAWS, PUBLIC RECORD LAWS, COMPETITIVE
10 BIDDING LAWS, AND INTELLECTUAL PROPERTY STANDARDS.
11 AND IT WOULD ALSO TRANSFER FROM THE CHAIR
12 INTELLECTUAL PROPERTY NEGOTIATIONS TO THE PRESIDENT.
13 CURRENTLY THE WAY PROPOSITION 71 WAS DESIGNED
14 NEGOTIATIONS ARE IN THE HANDS OF THE CHAIR.
15 EXECUTION OF THE AWARDS IS IN THE HANDS OF THE
16 PRESIDENT, AND THERE'S A CHECK AND ADDITIONAL LAYERS
17 OF PROTECTION TO PROTECT THE PUBLIC INTEREST.

18 THE BILL WOULD ELIMINATE THE
19 PREAPPLICATION REVIEW PROCESS. WE'VE DISCUSSED THIS
20 BEFORE AND, IN FACT, THE BOARD HAS SET UP A
21 SCIENTIFIC ISSUES SUBCOMMITTEE TO TAKE A CLOSER LOOK
22 AT THAT PROCESS TO DETERMINE WHETHER IMPROVEMENTS
23 COULD BE MADE TO IT.

24 IT WOULD ELIMINATE THE CAP OR PURPORTS TO
25 ELIMINATE THE CAP ON SCIENTISTS SERVING ON THE

BARRISTERS' REPORTING SERVICE

1 GRANTS WORKING GROUP. WE'VE ADDRESSED THIS ISSUE IN
2 THE PAST AS WELL, AND THE STAFF HAS MADE VERY CLEAR
3 THAT THE LIMIT ON SCIENTISTS ON THE GRANTS WORKING
4 GROUP DOES NOT ACT AS A BARRIER TO THE AGENCY'S
5 ABILITY TO EXPEDITIOUSLY REVIEW THE GRANTS. AND, IF
6 ANYTHING, ADDING MEMBERS MIGHT ACTUALLY INCREASE THE
7 TIME IT TAKES TO REVIEW GRANTS BECAUSE WE'D HAVE TO
8 ACCOMMODATE ADDITIONAL POINTS OF VIEW, WHICH WITH A
9 29-MEMBER BOARD, I'M SURE YOU CAN APPRECIATE.

10 AND, FINALLY, THE BILL WOULD, AS THE
11 SENATE BILL 1565 DID, TAKE CIRM'S INTELLECTUAL
12 PROPERTY REGULATIONS WHICH RELATE TO ACCESS TO
13 UNINSURED CALIFORNIANS AS WELL AS A PRICING
14 MECHANISM FOR STATE- AND LOCAL-GOVERNMENT FUNDED
15 PROGRAMS AND PLACE THOSE IN STATUTE. CURRENTLY THE
16 BOARD HAS THE AUTHORITY TO STRIKE A BALANCE TO
17 ENSURE THAT CALIFORNIANS RECEIVE SOME BENEFIT FROM
18 THEIR INVESTMENT IN STEM CELL RESEARCH WITH THE NEED
19 TO ENSURE THAT THE DEVELOPMENT OF THERAPIES IS NOT
20 UNNECESSARILY HINDERED.

21 THIS BILL WOULD REMOVE THAT AUTHORITY AND
22 PLACE THE REGULATIONS IN A STATUTE. AND IN LIGHT OF
23 THE UNCERTAIN HEALTHCARE DEBATE IN THIS COUNTRY, THE
24 EARLY STAGES OF DEVELOPMENT OF STEM CELL THERAPIES
25 GENERALLY, IT POSES SIGNIFICANT CHALLENGES TO THE

BARRISTERS' REPORTING SERVICE

1 AGENCY TO MAKE SURE THAT THAT BALANCE IS --

2 MR. TORRES: THANK YOU. MR. CHAIRMAN, I
3 MOVE THAT WE RECOMMEND THAT THIS SENATE BILL GO TO
4 INTERIM STUDY. I'D LIKE TO HAVE A SECOND ON THAT.

5 MR. ROTH: SECOND.

6 MR. TORRES: SECOND BY DUANE ROTH.

7 LET ME EXPLAIN TO YOU WHAT THAT MEANS.
8 RATHER THAN ENGAGE IN A PROCESS WHERE WE BECOME
9 ADVERSARIES, WHICH I DON'T THINK ANY OF US WANT TO
10 DO, THE LEGISLATURE PROVIDES FOR AN OPPORTUNITY
11 WHERE THERE ISN'T SIGNIFICANT SUPPORT OR A MAJOR
12 OPPOSITION TO LEGISLATION TO ALLOW IT TO GEL IN
13 WHAT'S CALLED INTERIM STUDY WHERE THE CHAIR OF THAT
14 POLICY COMMITTEE CAN HOLD A HEARING TO FLESH OUT
15 JUST WHAT THE ISSUES ARE.

16 I DO NOT THINK THAT THE STAFF OF THIS
17 COMMITTEE HAS HAD THE TIME TO DO THAT. AND I WOULD
18 RATHER EMBRACE THE OPPORTUNITY FOR AN OVERSIGHT
19 HEARING SO WE CAN PUT ON THE RECORD HOW MUCH WE HAVE
20 COMPLIED WITH SO MANY OF THESE ISSUES AND OF THESE
21 AUDITS. AND QUITE FRANKLY, I THINK IT'S
22 DISINGENUOUS THAT THE LEGISLATURE DOESN'T HAVE AN
23 APPROPRIATION WHICH WOULD IMMEDIATELY PUT INTO
24 SUSPENSE FOR AT LEAST THE 200,000 THAT IT COSTS THE
25 STATE BOARD OF AUDIT TO EXPEND IN ADDITION TO THE

BARRISTERS' REPORTING SERVICE

1 200,000 THAT WE HAVE TO EXPEND TO CONDUCT ONE AUDIT,
2 ONE AUDIT.

3 IT'S ALSO CLEAR THAT NO ONE HAS READ THIS
4 2006 SCIENTIFIC STRATEGY PLAN, STRATEGIC PLAN, THAT
5 WAS IMPLEMENTED BEFORE YOUR ARRIVAL ON OUR PACIFIC
6 SHORES, THESE PACIFIC SHORES. AND IT WAS AMENDED
7 AGAIN IN 2009. AGAIN, NO ONE READ IT. AND THEREIN
8 THAT LANGUAGE IS A SCIENTIFIC REVIEW OF SUBSTANCE OF
9 WHAT WE'RE DOING, WHERE WE'RE GOING, AND HOW WE'RE
10 GOING TO ACHIEVE IT. SO I BELIEVE THIS IS THE MORE
11 APPROPRIATE WAY TO GO, AND I WILL CONTINUE TO ARGUE
12 THAT WITH MEMBERS OF THE SENATE HEALTH COMMITTEE.

13 MR. KLEIN.

14 CHAIRMAN KLEIN: YES. JUST AS AN
15 ADDITIONAL COMMENT ON WHAT MR. HARRISON'S STATEMENTS
16 WERE. I'D LIKE TO POINT OUT THAT IN THE BILL AS
17 WRITTEN IT ATTEMPTS TO OVERRIDE THE SPECIFIC
18 PROVISION IN THE INITIATIVE THAT CALLS FOR LOAN
19 PROCEEDS TO BE COLLECTED AND REINVESTED IN LOANS AND
20 GRANTS BY REFERRING TO THESE AS BEING SUBJECT TO
21 INTELLECTUAL PROPERTY AGREEMENT AND THEN SAYING ALL
22 REVENUES FROM INTELLECTUAL PROPERTY AGREEMENTS GO TO
23 THE STATE'S GENERAL FUND.

24 CLEARLY THE INITIATIVE STATES REVENUES
25 FROM INTELLECTUAL PROPERTY AGREEMENTS, FROM IP

BARRISTERS' REPORTING SERVICE

1 ROYALTIES, AND LICENSING FEES GO BACK TO THE STATE,
2 BUT LOAN PROCEEDS COULDN'T BE RECYCLED.

3 NO. 2, I'D POINT OUT THAT IT IS VERY
4 IMPORTANT TO UNDERSTAND THAT TRANSFERRING THE BOARD
5 LEVEL OVERSIGHT OF CONFLICTS AND ACCOUNTABILITY TO
6 THE PRESIDENT WOULD PUT THE PRESIDENT IN THE
7 UNENVIABLE SITUATION OF HAVING TO REPORT ON THE
8 PEOPLE THAT HIRE HIM. IT'S KIND OF AN ILLOGICAL
9 REALLOCATION OF RESPONSIBILITY.

10 THERE'S A CONSTITUTIONAL STANDARD HERE.
11 YOU CAN'T PIECEMEAL GO THROUGH AND JUST DECIDE HOW
12 YOU WOULD HAVE WRITTEN THE INITIATIVE. THE
13 INITIATIVE WAS VOTED ON BY 7 MILLION PEOPLE. THE
14 SUPREME COURT SAYS THIS IS A PRECIOUS RIGHT OF THE
15 PUBLIC. IF YOU CONSTITUTIONALLY CAN CHANGE
16 RESPONSIBILITIES IN THIS BILL, YOU CAN THEN
17 THEORETICALLY CONSTITUTIONALLY, BECAUSE YOU HAVE A
18 PRECEDENT, CHANGE ANYTHING IN THE INITIATIVE.

19 SO IT'S VERY IMPORTANT TO RESPECT THAT AND
20 UNDERSTAND WE HAVE A HISTORY IN 2005 AND 2006 OF
21 SITTING WITH THE LEGISLATURE, TAKING THEIR INPUT,
22 WORKING WITH THEM, PUTTING INTO OUR BYLAWS
23 PROVISIONS THAT THE LEGISLATURE SUGGESTED, AND WE
24 CANNOT CHANGE THOSE PROVISIONS WITHOUT A VOTE AND A
25 PUBLIC REPORT IN ADVANCE TO THE LEGISLATURE SO THEY

BARRISTERS' REPORTING SERVICE

1 CAN DECIDE AT THAT TIME TO TAKE ACTION IF THEY NEED
2 TO.

3 MR. TORRES: THANK YOU, MR. KLEIN. MS.
4 LANSING.

5 MS. LANSING: I AGREE TOTALLY WITH YOUR
6 SUGGESTION, ART. I THINK IT'S THE RIGHT ONE. I
7 THINK IT'S THE FAIR ONE. AND ALSO I WANT TO JUST
8 SAY FOR THE RECORD SHOULD WE FIND A WAY TO IMPROVE
9 OURSELVES AND TO BETTER OURSELVES, WE WILL OPEN IT
10 AND EMBRACE IT AS WELL. SO I THINK THIS IS A VERY
11 GOOD PROCESS FOR BOTH SIDES TO GO THROUGH.

12 MR. TORRES: THANK YOU, SHERRY. MR. ROTH.

13 MR. ROTH: CALL THE QUESTION.

14 MR. TORRES: QUESTION HAS BEEN CALLED FOR.
15 ARE THERE PUBLIC COMMENTS? NO PUBLIC COMMENT. CALL
16 THE ROLL, PLEASE. ALL THOSE IN FAVOR SIGNIFY BY
17 SAYING AYE.

18 (CHORUS OF AYES.)

19 MR. TORRES: TELEPHONE.

20 MS. KING: AND I WILL JUST CHECK. I KNOW
21 MS. SAMUELSON HAD TO LEAVE US.

22 MR. SHESTACK: AYE.

23 MS. KING: THANK YOU. MR. SHESTACK'S VOTE
24 IS AYE.

25 MR. TORRES: ANY OPPOSED? SILENCE IS

BARRISTERS' REPORTING SERVICE

1 GOLDEN.

2 ALL RIGHT. WE'LL MOVE ON. THAT MOTION
3 CARRIES.

4 THE NEXT LEGISLATION, I HAD ASKED
5 ASSEMBLYMEMBER PORTANTINO NOT TO COME, ALTHOUGH HE
6 WANTED TO, AND I WANT TO THANK HIM FOR HIS
7 GRACIOUSNESS FOR AGREEING TO, AND THAT'S AB 52.

8 MR. HARRISON.

9 MR. HARRISON: AB 52 IS A BILL THAT WOULD
10 ESTABLISH AN UMBILICAL CORD BLOOD PROGRAM IN THE
11 STATE OF CALIFORNIA. UNDER EXISTING LAW, THE
12 DEPARTMENT OF PUBLIC HEALTH IS REQUIRED TO ESTABLISH
13 SUCH A PROGRAM. BUT THE DEPARTMENT OF PUBLIC HEALTH
14 CURRENTLY ADMINISTERS 300 OTHER PROGRAMS, AND THEY
15 HAVE EXPRESSED SOME RELUCTANCE TO ADMINISTERING THIS
16 PROGRAM.

17 IT WOULD BE FUNDED BY THE ADDITION OF \$2
18 TO THE CURRENT \$7 FEE ON COPIES OF DUPLICATE BIRTH
19 CERTIFICATES. THE REVENUES FROM THAT \$2-INCREASE IN
20 THE FEE WOULD GO TO THE UMBILICAL CORD BLOOD
21 COLLECTION PROGRAM FUND. THE AUTHOR HAS PROPOSED
22 THAT CIRM MIGHT BE AN APPROPRIATE PLACE TO HOUSE AND
23 TO ADMINISTER THE PROGRAM.

24 AND AT THE LEGISLATIVE SUBCOMMITTEE, THE
25 ASSEMBLYMEMBER MADE A PRESENTATION, AND CHAIR OF THE

BARRISTERS' REPORTING SERVICE

1 LEGISLATIVE SUBCOMMITTEE, VICE CHAIR TORRES,
2 RECOMMENDED THAT STAFF BE REQUESTED TO CONDUCT AN
3 ANALYSIS OF THE ALTERNATIVES AVAILABLE TO ADVANCE
4 THE GOALS OF THE PROGRAM, NOT NECESSARILY HOUSING IT
5 WITHIN CIRM, BUT THOSE WOULD INCLUDE SCIENTIFIC
6 ISSUES, PROGRAMMATIC ISSUES, AND ADMINISTRATIVE
7 ISSUES, AND LIABILITY ISSUES.

8 MR. TORRES: SO THE MOTION WAS, IN
9 CONSULTATION WITH MR. ROTH AND ALSO IN MY
10 CONVERSATIONS WITH BLOOD BANKS ACROSS THE STATE,
11 ESPECIALLY IN SAN DIEGO, WERE THAT THERE ARE SO MANY
12 COMPLEX ISSUES INVOLVED IN ESTABLISHING A STATEWIDE
13 CORD BLOOD BANK, NOT THE LEAST OF WHICH IS SOME
14 PEOPLE ARGUE THAT WE SHOULD ONLY HAVE A NATIONAL
15 CORD BLOOD BANK, OUR THOUGHTS IN CONSULTATION WITH
16 PRESIDENT TROUNSON WAS TO COME UP WITH A CONCEPT
17 WHERE THE STAFF WOULD LOOK INTO ALL OF THE ISSUES,
18 LIABILITY ISSUES, SUBSTANTIVE ISSUES, LOGISTIC
19 ISSUES, FINANCIAL ISSUES, AND SEE WHETHER OR NOT AT
20 SOME POINT WE MIGHT DECIDE RATHER THAN HOUSE THIS,
21 AS MR. PORTANTINO DOESN'T PRESENTLY PROPOSE, BUT
22 MIGHT, HOUSE THIS -- HAVE AN RFA PUT OUT TO SUGGEST
23 WHAT'S OUT THERE AND SEE WHAT KIND OF RESPONSE WE
24 MIGHT GET.

25 FIRST LET'S DO OUR HOMEWORK AS TO WHAT THE

BARRISTERS' REPORTING SERVICE

1 VARIABLES ARE. SO THAT WAS MY MOTION, WHICH WAS
2 ACCEPTED BY THE LEGISLATIVE SUBCOMMITTEE. AND I SO
3 MOVE. IS THERE A SECOND?

4 MS. LANSING: SECOND.

5 MR. TORRES: SECOND BY MS. LANSING.
6 PRESIDENT TROUNSON, YOUR RESPONSE.

7 DR. TROUNSON: WELL, YOU KNOW, I THINK YOU
8 REQUESTED US TO DO THIS WITHIN THREE TO FIVE MONTHS.
9 AT THREE MONTHS I THINK WE WERE TO GIVE YOU A REPORT
10 ON PROGRESS. AND WE'VE STARTED A DISCUSSION ABOUT
11 WHERE THOSE RESOURCES CAN BE FOUND TO INVESTIGATE
12 THIS.

13 IT'S A PRETTY SUBSTANTIVE ISSUE. AND SO I
14 DON'T WANT TO SORT OF SAY THAT THIS IS AN EASY
15 PROCESS, BUT I THINK WE HAVE AN IDEA OF HOW WE
16 SHOULD GO ABOUT IT, AND WE'LL KEEP YOU INFORMED AS
17 WE MOVE FORWARD ABOUT WHEN WE CAN ACTUALLY DELIVER
18 THE FINAL SET OF RECOMMENDATIONS OR WHITE PAPER TO
19 YOU TO CONSIDER.

20 MR. TORRES: THANK YOU, MR. PRESIDENT. AS
21 YOU CAN SEE FROM THE BILL, MEMBERS, IT HAS
22 BIPARTISAN SUPPORT, AND THAT'S WHY WE FELT IT WAS
23 IMPORTANT TO GIVE IT SERIOUS CONSIDERATION. I THINK
24 THIS FALLS IN THAT SUBSTANTIVE DIRECTION.

25 CALL FOR THE -- I'M SORRY. THE MOTION IS

BARRISTERS' REPORTING SERVICE

1 TO DIRECT THE STAFF UNDER THE LEADERSHIP OF DR.
2 TROUNSON TO REVIEW ALL THE ISSUES INVOLVED IN THE
3 ESTABLISHMENT OF A STATE CORD BLOOD BANK IN
4 CALIFORNIA AND WHETHER OR NOT WE SHOULD PROCEED TO
5 PERHAPS ISSUE AN RFA TO DO SO. NOT TO HOUSE IT
6 WITHIN CIRM BECAUSE WE'RE NOT CAPABLE OF DOING THAT,
7 BUT WHETHER WE SHOULD PROCEED OUTSIDE TO HAVE
8 SOMEONE ELSE APPLY IN RESPECT TO AN RFA THAT MAY OR
9 MAY NOT BE ISSUED, DEPENDENT ON THEIR
10 RECOMMENDATION, WITHIN THREE TO FIVE MONTHS.

11 ANY OPPOSITION OR PUBLIC COMMENT RATHER?

12 MS. GIBBONS: WITHOUT A RESCUE FROM CIRM
13 OR SOME OTHER OUTSIDE INTERVENTION THAT MAY COME
14 FROM THIS RFA, THIS PROGRAM IS LIKELY TO GO AWAY; IS
15 THAT A CORRECT UNDERSTANDING?

16 MR. TORRES: NO. IT'S NOT LIKELY TO GO
17 AWAY. THERE ARE SOME BLOOD BANKS THAT ARE LOOKING
18 INTO IT IN A LOCAL AREA. FOR EXAMPLE, SAN DIEGO DID
19 START THIS EFFORT, THEN RECEDED BACK, NOW THEY'RE
20 LOOKING AT IT AGAIN, WHETHER TO DO IT ON THEIR OWN.
21 OUR INTERESTS MAY SPARK MORE INTEREST FROM OTHER
22 AREAS OR OTHER BLOOD BANKS IN CALIFORNIA.

23 THE OTHER NOTION IS THAT THIS MAY NOT BE
24 JUST ONE PROJECT OR ONE BLOOD BANK COMING FORWARD
25 AND SAY WE WANT TO APPLY. IT MAY BE ONE OR THREE OR

BARRISTERS' REPORTING SERVICE

1 FOUR, NOT NECESSARILY JUST ONE STATE CORD BLOOD
2 BANK.

3 CHAIRMAN KLEIN: ART, IF I UNDERSTOOD
4 CORRECTLY, AS WELL TO LEGISLATIVE SUBCOMMITTEE, THE
5 RECOMMENDATION RANGE COULD INCLUDE OUR AGENCY ON A
6 CONTRACT BASIS OVERSEEING AND MONITORING THIS AS
7 LONG AS THERE'S SUFFICIENT REVENUE AND STAFFING TO
8 CARRY OUT THAT FUNCTION.

9 SO THIS IS STAFFING THAT WOULD OCCUR
10 OUTSIDE OF OUR CURRENT CAP AND REVENUE FROM OUTSIDE
11 OF OUR CURRENT CAP BECAUSE IT IS A SEPARATE FUNCTION
12 THAT WOULD BE SUPPORTED BY LEGISLATION AUTHORIZING
13 THAT SEPARATE FUNCTION.

14 SO THERE'S A RANGE OF POSSIBILITIES FOR
15 THE STAFF TO LOOK AT. MY UNDERSTANDING IS THEY'RE
16 LOOKING AT THE FULL RANGE.

17 MS. LANSING: I JUST WANT TO ADD THAT THIS
18 IS WHY IT'S SUCH A WONDERFUL STAFF. THEY'RE GOING
19 TO LOOK AT IT, THEY'RE GOING TO TELL US WHAT'S
20 FEASIBLE, WHAT'S NOT FEASIBLE. IF YOU NEED MORE
21 TIME, BECAUSE I SENSED IN YOUR VOICE THAT THIS THREE
22 TO FIVE MONTHS WAS MAKING YOU VERY NERVOUS, THEN YOU
23 WILL COME BACK TO US AND SAY I NEED SIX MONTHS.
24 BECAUSE WE WANT YOU TO DO A THOROUGH STUDY. WE WANT
25 WHAT'S IN THE BEST INTEREST OF EVERYONE. I'M VERY

BARRISTERS' REPORTING SERVICE

1 COMFORTABLE WITH A STUDY OF THIS, AND I DON'T KNOW
2 WHAT'S GOING TO COME BACK. NONE OF US DO.

3 MR. TORRES: ANY OTHER COMMENTS FROM
4 MEMBERS OF THE BOARD? ANY PUBLIC COMMENT? SEEING
5 NONE, WE'LL CALL THE ROLL. ALL THOSE IN FAVOR
6 SIGNIFY BY SAYING AYE.

7 (CHORUS OF AYES.)

8 MR. TORRES: ALL THOSE OPPOSED? MEMBERS
9 ON THE --

10 MS. KING: JON SHESTACK, YOUR VOTE PLEASE.
11 IT APPEARS THAT MR. SHESTACK MAY HAVE LEFT US, BUT
12 WE DO HAVE A QUORUM WITHOUT HIM, SO THAT MOTION
13 CARRIES.

14 MR. TORRES: LASTLY, I JUST WANT TO THANK
15 THE MEMBERS OF THE LEGISLATIVE SUBCOMMITTEE FOR YOUR
16 TREMENDOUS INVOLVEMENT AND INPUT. AND ALSO TO EACH
17 OF THE BOARD MEMBERS ON THIS HISTORIC VISIT TO THE
18 CAPITOL. I THINK EACH OF YOU REALLY HAVE DONE AN
19 INCREDIBLE JOB OF VISITING WITH LEGISLATORS, GETTING
20 THEIR PERSPECTIVES. I'M SORRY NOT MANY OF THEM HAVE
21 COME IN HERE TODAY BECAUSE THEY ARE IN SESSION, BUT
22 I KNOW SOME OF YOU HAVE MEETINGS THIS AFTERNOON AS
23 WELL. SO GOD SPEED AND THANK YOU. MR. CHAIRMAN.

24 CHAIRMAN KLEIN: SO WE ARE NOW GOING TO
25 ADJOURN TO AN EXECUTIVE SESSION. AND WHAT ARE THE

BARRISTERS' REPORTING SERVICE

1 INSTRUCTIONS ON THE LOCATION OF THAT EXECUTIVE
2 SESSION?

3 MS. KING: SO THE EXECUTIVE SESSION IS
4 GOING TO BE IN ROOM 447 IN THE RESTORED SIDE OF THE
5 BUILDING.

6 CHAIRMAN KLEIN: AND WHO WILL LEAD US TO
7 THAT? JENNA PRYNE WILL LEAD US TO THE EXECUTIVE
8 SESSION.

9 MR. HARRISON, IF YOU COULD READ OR RECITE
10 THE STATUTORY AUTHORIZATION FOR THE EXECUTIVE
11 SESSION AFTER MELISSA KING FINISHES HER COMMENT.

12 MS. KING: LUNCH IS ALSO PREPARED FOR THE
13 BOARD MEMBERS, AND THAT IS ALSO ON THE RESTORED SIDE
14 OF THE BUILDING. I'M JUST GOING TO SUGGEST, I KNOW
15 PEOPLE ARE GETTING HUNGRY, THAT FOLLOWING THE
16 EXECUTIVE SESSION, THE BOARD COULD GO TO LUNCH.
17 UNFORTUNATELY WE CAN'T DO IT BEFORE BECAUSE WE CAN'T
18 EAT IN THE ROOM WHERE WE'RE DOING THE CLOSED SESSION
19 AND THERE'S NO PLACE WHERE WE CAN EAT THAT IS A
20 PRIVATE ROOM. SO I JUST WANT TO SUGGEST THAT WE GO
21 TO LUNCH IMMEDIATELY FOLLOWING THAT INSTEAD OF
22 COMING BACK HERE.

23 CHAIRMAN KLEIN: TAKE YOUR MATERIALS WITH
24 YOU. MR. HARRISON, COULD YOU PLEASE GIVE US THE
25 STATUTORY AUTHORITY.

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: THE BOARD WILL BE MEETING
2 IN CLOSED SESSION TO DISCUSS PERSONNEL PURSUANT TO
3 HEALTH AND SAFETY CODE SECTION 125290.30 AND
4 GOVERNMENT CODE SECTION 11126.

5 (THE MEETING WAS THEN ADJOURNED AT 12:56 P.M.)
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BARRISTERS' REPORTING SERVICE

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

STATE CAPITOL BUILDING
ROOM 4202
SACRAMENTO, CALIFORNIA
ON
MARCH 11, 2010

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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